Revised Reregistration Eligibility Decision for MSMA, DSMA, CAMA, and Cacodylic Acid

August 10, 2006

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: August 10, 2006

Subject: Revised "Reregistration Eligibility Decision for MSMA, DSMA, CAMA, and Cacodylic Acid" Document

From: Lance Wormell, Chemical Review Manager
Reregistration Branch 2
Special Review and Reregistration Division

To: Organic Arsenical Herbicides Docket (EPA-HQ-OPP-2006-0201)

EPA originally published the "Reregistration Eligibility Decision for MSMA, DSMA, CAMA, and Cacodylic Acid" (EPA 738-R-06-021) in the electronic docket on August 9, 2006. EPA has since identified and corrected a typographical error on page 22. The cancer slope factor for inorganic arsenic used to calculate the exposure level in drinking water was incorrectly listed as 3.67×10^{-3} $(mg/kg/day)^{-1}$. The value has since been corrected to 3.67 $(mg/kg/day)^{-1}$. The typographical change in the document does not alter EPA's calculations or conclusions and the current document should be used in place of the previous version.

United States Environmental Protection Agency

Office of Prevention, Pesticides And Toxic Substances (7508P)

EPA 738-R-06-021
July 2006

Reregistration Eligibility Decision for MSMA, DSMA, CAMA, and Cacodylic Acid

List B

Case Nos. 2395, 2080

Reregistration Eligibility Decision (RED) Document

for

MSMA, DSMA, CAMA, and Cacodylic Acid

Approved by: Debra Edwards

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Date: July 31, 2006

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Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EXAMS	Exposure Analysis Modeling System
EUP	End-Use Product
FCID	Food Commodity Intake Database
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter

mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

I. Introduction

This document is the Environmental Protection Agency's (EPA or "the Agency") reregistration eligibility determination (RED) and tolerance reassessment for all currently registered uses of MSMA, DSMA, CAMA, and cacodylic acid (collectively referred to as the "organic arsenical herbicides"). This document summarizes the human health and environmental risks as well as the tolerance reassessment for the organic arsenical herbicides.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all data submitted to the Environmental Protection Agency. Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review in this case is to reassess the potential risks arising from the currently registered uses of the organic arsenical herbicides, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticides meet the "no unreasonable adverse effects" criteria of FIFRA.

EPA's decision under FIFRA is based on a thorough evaluation of both the risks and benefits of the uses of the organic arsenical herbicides. While EPA has identified some risk associated with the direct use of these herbicides, the Agency's primary concern is the potential for applied organic arsenical products to transform to a more toxic inorganic form of arsenic in soil with subsequent transport to drinking water. The Agency's risk assessment – bolstered by actual field monitoring data in both surface and ground water – estimates levels of arsenic in drinking water from pesticidal uses that raise a concern for cancer risk. Given that estimated drinking water exposure from the pesticidal uses alone exceeds EPA's level of concern and that alternative herbicides are readily available, EPA concludes that the benefits do not outweigh the risks and that all uses for the active ingredients MSMA, DSMA, CAMA, and cacodylic acid are ineligible for reregistration.

The Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA), requires EPA to reassess by August 3, 2006 all tolerances that were in effect as of August 3, 1996. In order for a pesticide tolerance to remain in effect, EPA must generally determine with reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue.

Given that estimated drinking water exposure from the pesticidal uses alone exceeds EPA's level of concern, EPA concludes that existing tolerances listed under 40 CFR §180.289 (a)(1) and 40 CFR §180.311 (a)(1) do not meet the reasonable certainty of no harm standard under FFDCA/FQPA.

Risks summarized in this document are those that result only from the use of the organic arsenical herbicides. The Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to the organic arsenical herbicides. EPA has not assumed that the organic arsenical herbicides share a common mechanism of toxicity with other compounds. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism of toxicity on EPA's website at http://www.epa.gov/pesticides/cumulative/.

The document consists of six sections: Section I (Introduction) contains the regulatory framework for reregistration/tolerance reassessment; Section II (Chemical Overview) gives an overview of the chemicals and their uses; Section III (Summary of Organic Arsenical Herbicides Risk Assessments) summarizes the human health and ecological risk assessments; Section IV (Risk Management, Reregistration, and Tolerance Reassessment Decisions) presents the Agency's reregistration eligibility, tolerance reassessment, and risk management decisions; Section V (What Registrants Need to Do) presents next steps for the registrants; and the appendices that list related support documents and other information. Risk assessments and other support documents cited in this RED are available at http://www.regulations.gov in docket number EPA-HQ-OPP-2006-0201.

II. Chemical Overview

The registered pesticides assessed in this RED, collectively referred to as the "organic arsenical herbicides," are monosodium methanearsonate (MSMA), disodium methanearsonate (DSMA), calcium acid methanearsonate (CAMA), cacodylic acid (dimethylarsinic acid), and cacodylic acid's sodium salt (sodium cacodylate). For ease of discussion, the sodium salt of cacodylic acid and cacodylic acid are treated as one and are also referred to as dimethylarsonic acid (DMA). MSMA, DSMA, and CAMA are collectively referred to as monomethylarsonic acid (MMA, also known as MAA or methylarsonic acid). In cases where chemical-specific issues are discussed, the individual pesticide name (i.e., MSMA, DSMA, or CAMA) is used. Table 1 presents the chemicals assessed in the organic arsenic herbicide RED.

Table 1. Registered Pesticides Assessed in the Organic arsenical herbicides RED

Case Number	CAS Number	PC Code	Chemical Name	Name Used in RED Documents	MMA or DMA
2395	2163-80-6	013803	monosodium methanearsonate	MSMA	MMA
2395	144-21-8	013802	disodium methanearsonate	DSMA	

2395	5902-95-4	013806	calcium acid methanearsonate	CAMA	
2380	75-60-5	012501	cacodylic acid	cacodylic acid	DMA
2380	124-65-2	012502	cacodylic acid, sodium salt		

A. Regulatory History

The organic arsenical herbicides were first registered in the United States for use as herbicides in the 1950s (DSMA) and 1960s (MSMA, CAMA, cacodylic acid). Currently there are approximately 90 end-use products containing MSMA, 25 end-use products containing DSMA, 4 end-use products containing CAMA, and 35 end-use products containing cacodylic acid. There are currently 3 tolerances for MSMA and DSMA (expressed as methanearsonic acid) listed in Chapter 40 of the Code of Federal Regulations (40 CFR) 180.289 and 1 tolerance for cacodylic acid listed in 40 CFR 180.311; no tolerance exists for CAMA. Previously, tolerances existed for cacodylic acid on milk, meat, poultry, and eggs (MMPE). These MMPE tolerances were revoked in February 2004 (40 CFR Part 180 [OPP–2003–0344; FRL–7338–3]).

Tolerances previously existed for several inorganic arsenical pesticides (e.g., lead arsenate). EPA conducted a Special Review in several phases for the various uses of inorganic arsenical pesticides based primarily on concern for carcinogenicity. The last remaining uses – including lead arsenate used as a growth regulator on citrus, calcium arsenate used as an herbicide on turf, sodium arsenite used as a fungicide on grapes and arsenic acid used as a desiccant on okra for seed and cotton – were voluntarily cancelled in the late 1980s and the early 1990s, and the associated tolerances have been revoked. Historically, the use of arsenic acid on cotton had been as high as 6.8 million pounds of active ingredient per year.

In addition, the U.S. Food and Drug Administration (FDA) has established tolerances for total arsenic in edible tissues and in eggs of chickens and turkey as well as in edible tissues of swine as listed in 21 CFR 556.60. Accordingly, EPA's dietary analyses include estimates of possible arsenic residues in poultry and swine commodities making use of monitoring data from the FDA Total Diet Study. The poultry and swine tolerances listed in 21 CFR 556.60 are regulated by FDA and are not included in or affected by this tolerance reassessment decision.

The reregistration of MSMA is being supported by Albaugh, Inc. and the MAA Research Task Force (MAATF) comprising APC Holdings Corp., KMG-Bernuth, Inc., and Luxembourg-Pamol, Inc.; DSMA is being supported by the MAATF; CAMA is being supported by APC Holdings Corp.; and cacodylic acid is being supported by Luxembourg-Pamol, Inc. The organic arsenical herbicides are not registered for use in the European Union or in Canada. MSMA was previously registered in Canada for forestry use (tree-injectable only). The registrant did not provide the necessary supporting data in 2003 and the products were listed as "discontinued" as of August 2005. Existing products may not be used after December 2008. Cacodylic acid was previously registered in Canada from 1968 to 1972. CAMA was registered in Canada as an insecticide from 1928 to 1972.

Data Call-Ins (DCI) for MSMA, DSMA, CAMA, and cacodylic acid were issued in 1991, 1993, and 1995. The DCIs required chemical identity, toxicology, field trial, ecological, and other data.

B. Use Profile

MSMA and DSMA are herbicides registered for weed control on cotton, for turf grass and lawns, and under trees, vines, and shrubs. CAMA is an herbicide registered for post-emergent weed control on lawns. Cacodylic acid is a defoliant and herbicide registered for weed control under non-bearing citrus trees, around buildings and sidewalks, and for lawn renovation. A summary of the uses supported for reregistration and assessed in EPA's RED is presented in Table 2. These uses reflect the information in the proposed Master Labels submitted by the MAATF in December 2005. The proposed Master Labels are available at http://www.regulations.gov in docket number EPA-HQ-OPP-2006-0201.

Table 2. Summary of Organic Arsenical Herbicide Uses Evaluated for Reregistration

Chemical	Use Site	Application Methods	Application Rates (lb. ai/A)[1]	Applications Per Year
MSMA	Cotton	By ground or air: pre-plant or post-plant (up to cracking); by ground or air: post-emergent (as over the top broadcast spray); by ground: post-emergent (directed spray application)	0.8 - 1.7	1 - 2
	Grasses Grown for Seed in Pacific Northwest only (Ryegrass, Fescue, and Bluegrass)	Pacific Northwest apply before boot stage	5.3	1
	Lawns, Ornamental Turf, and Sod Farms	By ground only on athletic fields, golf courses, parks; by ground on well established actively growing turf; by ground on established Bermuda grass & zoysiagrass; sod farms	1.9 - 3.4	4
	Nonbearing Orchards and Vineyards	Ground directed	3.5	3
	Noncrop Areas	Ground application	3.9	4

DSMA	Cotton	By ground or air pre-plant or post-plant (up to cracking); by ground or air: post-emergent (as over the top broadcast spray); by ground post-emergent (directed spray application); by ground post-emergent (directed band application) based on 40 inch row spacing)	1.7	1 - 2
	Grasses Grown for Seed in Pacific Northwest only (Ryegrass, Fescue, and Bluegrass)	Pacific Northwest apply before boot stage	3.3	1
	Lawns, Ornamental Turf, and Sod Farms	By Ground on well established actively growing turf; sod farms	2.5	4
	Nonbearing Orchards and Vineyards	Ground directed	3.7	3
	Noncrop Areas	Ground application	3.9	4
CAMA[2]	Turfgrass, Lawns, Ornamental Turf, Turf Grown for Sod	By ground only on athletic fields, golf courses, parks; by ground on well established actively growing turf; by ground on established Bermuda grass and zoysiagrass	2.2 - 4.4	2 - 4
Cacodylic acid	Cotton	Preconditioning for defoliation, defoliation	0.9375 - 2.0	1 - 2
	Lawns, Ornamental Turf	Lawn renovation, lawn edging	7.3 - 7.7	2 - 4
	Non-Crop Areas, Ornamentals	Non-crop; ornamentals	7.3	6
	Nonbearing Citrus	Ground directed	4.96	3

[1] Application rates for MSMA, DSMA, and CAMA are expressed as MMA equivalent
[2] One broadcast application per year with additional applications as spot treatment only; in Florida all applications as spot treatment only

1. Formulations

MSMA is formulated as a liquid concentrate and a ready-to-use liquid. DSMA is formulated as a liquid concentrate and a wettable powder. CAMA is formulated as a liquid concentrate and a ready-to-use solution. Cacodylic acid is formulated as a liquid concentrate, a pressurized liquid, and a ready-to-use solution. There are approximately 250 registered products.

2. Application Methods

MSMA and DSMA are applied by aircraft, groundboom, rights-of-way sprayer, turf handgun sprayer, low pressure handwand sprayer, and sprinkler can. CAMA is applied by commercial applicators using a low-pressure handwand sprayer or handgun sprayer and is applied by homeowner applicators using a low pressure handwand sprayer, hose-end sprayer, and ready-to-use "trigger pump" sprayer. Cacodylic acid is applied using aircraft, groundboom sprayer, rights-of-way sprayer, handgun sprayer, low pressure handwand sprayer, and sprinkling can.

3. Usage

Each year approximately 3,000,000 pounds of MSMA or DSMA and 100,000 pounds of cacodylic acid are applied in the US based on EPA's Screening Level Use Analysis data; no data are available for CAMA. The majority of the organic arsenical herbicides is applied to cotton and turf (residential and golf courses).

III. Summary of Organic Arsenical Herbicides Risk Assessments

The purpose of this section is to summarize EPA's human health and ecological risk conclusions for the organic arsenical herbicides to help the reader better understand EPA's risk management decisions. The full risk assessments and related supporting documents are available at http://www.regulations.gov in docket number EPA-HQ-OPP-2006-0201.

A. Background, Organic, Inorganic, and Total Arsenic

The element arsenic is ubiquitous and occurs naturally in many forms in the environment. In addition to these naturally occurring "background" (i.e., non-pesticidal) levels of arsenic, the RED document and support documents consider "organic arsenic," "inorganic arsenic," and "total arsenic." For ease of discussion, background arsenic refers to arsenic in the environment that is not as a result of organic arsenical pesticide use; organic arsenic refers to MMA (MSMA, DSMA, CAMA) and/or DMA (cacodylic acid); inorganic arsenic refers to the more toxic form found in water and soil; and total arsenic refers to the non-differentiated or "unspeciated" measure of arsenic (including background, organic, and inorganic) commonly used in regulatory levels.

Because arsenic is ubiquitous and exists in many forms in the environment, it is difficult to quantify the extent to which measured arsenic is organic versus inorganic and the extent to which measured arsenic – whether organic, inorganic, or total – is present due to organic arsenic herbicide use versus naturally occurring (i.e., background). To the extent possible, EPA considered background, organic, inorganic, and total arsenic in its assessments. However, concerns for cancer risk from drinking water were based on exposure from the pesticidal use alone. Due to the complex nature of arsenic transformation and the inability to distinguish between pesticidal and background contributions, EPA relied on conservative assumptions to estimate exposure and risk.

Below are several terms and definitions to keep in mind when reading this document and support documents:

Background arsenic: "Background" arsenic is used to describe arsenic in the environment that is present as a result of natural geological processes and/or as a result of anything other than organic arsenical herbicide use.
Organic arsenic: The "organic" form of arsenic includes the pesticides cacodylic acid, MSMA, DSMA, and CAMA; organic arsenic compounds can also be found naturally in the environment.
Inorganic arsenic: Found naturally in the environment, the "inorganic" form of arsenic is the more toxic form and is known to cause cancer in humans.
Total arsenic: "Total" arsenic is used to describe all the arsenic present in a sample regardless of its form (i.e., organic arsenic + inorganic arsenic) and source (i.e., background + pesticidal); EPA and state/Federal agencies measure and/or establish regulatory limits in soil and water for total arsenic.
Transformation: The process of arsenic changing forms (i.e., organic to inorganic or vice versa).
Speciating: Quantifying the concentration of inorganic and organic arsenic in a soil or water sample (as opposed to only total arsenic); "speciated" data provide a breakdown of organic and inorganic arsenic whereas "unspeciated" data provide only total arsenic.
Methylation and demethylation: The chemical process that transforms metals such as arsenic by the addition (methylation) or removal (demethylation) of methyl groups (CH_3) to the molecule.
Monomethyl methanearsonate (MMA): MMA refers to organic arsenic compounds with a single methyl group; in these assessments, the term "MMA" is used collectively to refer to MSMA, DSMA, and CAMA (salts of MMA that readily dissociate to MMA in water).
Dimethyl methanearsonate (DMA): DMA refers to organic arsenic compounds with two methyl groups such as cacodylic acid and its salt; since cacodylic acid and cacodylic acid salt are the only registered dimethyl organic arsenic herbicides, DMA and cacodylic acid are used interchangeably in this document.

1. Background Arsenic

Arsenic can be found everywhere but is found only occasionally as the free element because if its reactivity; instead, arsenic is usually found chemically combined as organic and inorganic compounds in soil, water, plants, animals, and products of decay or metabolism. The primary natural source of arsenic is from bedrock; it is also emitted from industrial processes such as smelting and results from various agricultural practices. EPA previously registered inorganic arsenic pesticides but these uses have since been cancelled.

Although it is possible to measure arsenic concentrations in water, soil, and air, arsenic introduced locally through human activities (e.g., applying organic arsenical herbicides) cannot be distinguished from arsenic that is present in the natural background. Likewise, arsenic resulting from the transformation of other arsenic sources that are either naturally present or introduced by human activities cannot be distinguished from arsenic resulting from pesticidal applications. Thus, background levels of arsenic are merely averages of individual snapshots of the arsenic concentrations that cannot be quantitatively attributed to natural and human activities (e.g., historical pesticidal uses, smelting).

Existing background surface water and groundwater arsenic concentrations can range from several parts per billion (ppb) to more than 50 ppb. Soil and sediment arsenic concentrations typically range from several parts per million (ppm) to more than 50 ppm. Arsenic concentrations in air range from 0.01 g/m^3 to as high as 0.75 g/m^3. Concentrations can be even higher in areas near bedrock outcrops and mine spoilings (water and soil) or in smelter emissions (air).

As discussed above, background arsenic concentrations cannot be quantitatively attributed to natural and human activities and are highly variable, so background arsenic cannot be expressed as a meaningful national average. However, EPA did consider background arsenic exposure in its dietary exposure estimates. For food, EPA used data in the FDA Total Diet Study (TDS) which measured all detectable arsenic including arsenic present from all pesticidal and background sources; thus, background arsenic exposure in food is reflected in the dietary risk estimates that used FDA TDS data. For residential, occupational, and ecological risk assessments EPA sought to assess impacts from use of the pesticide only.

2. Organic Arsenic

In this document, organic arsenic refers to the organic arsenical herbicides MSMA, DSMA, CAMA, and cacodylic acid. A detailed discussion of the properties of and estimated exposure to these chemicals is included in Section II and Section III of this document, respectively.

3. Inorganic Arsenic

As discussed above, arsenic exists in many different forms in the environment including organic and inorganic. Organic arsenic forms (e.g., MMA, DMA) and inorganic forms of arsenic have dissimilar toxicities and target organs. Inorganic arsenic is more toxic than organic arsenic. Exposure to inorganic arsenic can occur from background residues and, given time and under environmental conditions that favor the transformation to inorganic arsenic, the registered uses of the organic arsenicals. In some media (food, water, soil) and in some parts of the United States, the likelihood of exposure to inorganic arsenic is higher than in others.

Under FQPA, the Agency is required to consider all potential sources of exposure to the organic arsenicals and their metabolites and/or transformation products. Since monitoring reflects total arsenic (all species included) and there is potential for transformation and exposure to inorganic arsenic from the registered uses of the organic arsenicals, EPA performed a dietary (drinking water only) analysis for potential exposure to inorganic arsenic.

4. Total Arsenic

Total arsenic refers to the non-differentiated or unspeciated measure of arsenic. In monitoring programs, arsenic concentrations are typically measured and reported as total arsenic, regardless of the species (e.g., DMA, MMA, inorganic arsenic) or mixture of species that may be present, and regardless of the sources (i.e., pesticidal or background) that contributed to the total arsenic level.

The federal government and most states have established limits and/or screening levels for total arsenic exposure from a variety of sources such as drinking water, air, and soil. These limits or screening levels are established based on long-term human health risks from exposure to the more toxic inorganic form of arsenic and some also take into account technically feasible clean-up levels.

EPA estimated total arsenic that may be present as a result of organic arsenical herbicide use to allow for comparison to the Agency's established levels of concern.

B. Human Health Risk Assessment

EPA has conducted a human health risk assessment for the organic arsenical herbicides to support the reregistration eligibility decision. EPA evaluated the submitted toxicology, product and residue chemistry, and occupational/residential exposure studies as well as available open literature and determined that the data are adequate to support a reregistration eligibility decision. A summary of the human health risk assessment findings and conclusions is provided below; the full risk assessment is available at http://www.regulations.gov in docket number EPA-HQ-OPP-2006-0201.

1. Toxicity Profile

The toxicological databases for MMA (MSMA, DSMA, and CAMA) and DMA (cacodylic acid) are adequate to support a reregistration eligibility decision. MMA and DMA are considered toxicologically unique and were evaluated separately. Inorganic arsenic, a transformation product of MMA and DMA, is also toxicologically unique and was also evaluated separately. Data are sufficient for all exposure scenarios and for FQPA evaluation. Additional toxicity studies are not required.

The separation of MMA, DMA, and inorganic arsenic toxicities was the subject of a September 2005 EPA Scientific Advisory Board meeting (http://www.epa.gov/sab/panels/arsenic_review_panel.htm). Additional information on the distinct toxicities of organic arsenic (i.e., MMA and DMA) and inorganic arsenic is available in EPA's "Revised Science Issue Paper: Mode of Carcinogenic Action for

Cacodylic Acid (Dimethylarsinic Acid, DMA^V) and Recommendations for Dose Response Extrapolation" dated January 30, 2006.

a. Acute Toxicity Profiles

MSMA, DSMA, CAMA, and cacodylic acid have moderate to low acute toxicity via the oral, dermal, and inhalation routes (Category III and IV). They are moderate eye irritants (Category III), mild dermal irritants (Category IV), and not skin sensitizers. Tables 3, 4, 5, and 6 present the acute toxicity profiles for MSMA, DSMA, CAMA, and cacodylic acid, respectively.

Table 3. Acute Toxicity Profile for MSMA

Guideline No.	Study Type	MRID	Results	Toxicity Category
81-1	Acute Oral, rat	45405601*	LD_{50} = 2449 mg/kg (F) 3184 mg/kg (M) 2833 mg/kg (Combined)	III
81-2	Acute Dermal, rabbit	41890001*	LD_{50} > 2000 mg/kg	III
81-3	Acute Inhalation, rat	42604601*	LC_{50} = 2.20 mg/L	III
81-4	Primary Eye Irritation, rabbit	43840901*	Reversible conjunctival irritation	III
81-5	Primary Skin Irritation, rabbit	41892008[a]	Slight irritant	IV
81-6	Dermal Sensitization, guinea pig	41890002*	Not a sensitizer	
81-8	Acute Neurotoxicity	N/A		

Table 4. Acute Toxicity Profile for DSMA

Guideline No.	Study Type	MRID	Results	Toxicity Category
81-1	Acute Oral, rat	41892004	LD_{50} = 1935 (1631-2295) mg/kg (M&F)	III
81-2	Acute Dermal, rabbit	41892005	LD_{50} > 2000 mg/kg	III
81-3	Acute Inhalation, rat	41892006	LC_{50} > 6 mg/L	IV
81-4	Primary Eye Irritation, rabbit	41892007	Redness and swelling of the conjunctivae	III
81-5	Primary Skin Irritation, rabbit	41892008	No redness or swelling	IV
81-6	Dermal Sensitization, guinea pig	41890009	Not a sensitizer	
81-8	Acute Neurotoxicity	N/A		

Table 5. Acute Toxicity Profile for CAMA

Guideline No.	Study Type	MRID	Results	Toxicity Category
81-1	Acute Oral, rat	42880201	LD_{50} > 5000 mg/kg (M&F)	IV
81-2	Acute Dermal, rat	42900101	LD_{50} > 5000 mg/kg	IV
81-3	Acute Inhalation, rat	42900102	LC_{50} > 5 mg/L	IV
81-4	Primary Eye Irritation, rabbit	42900202	Mild eye irritant	III
81-5	Primary Skin Irritation, rabbit	42900203	Slight skin irritant	IV
81-6	Dermal Sensitization, rabbit	42900103	Not a sensitizer	
81-8	Acute Neurotoxicity	N/A		

Table 6. Acute Toxicity Profile for Cacodylic Acid

Guideline No.	Study Type	MRID	Results	Toxicity Category
870.1100	Acute Oral	41925601	LD_{50} (M&F) = 2800 mg/kg	III
870.1200	Acute Dermal	41892701	LD_{50} > 2000 mg/kg	III
870.1300	Acute Inhalation	41892702	LC_{50} (4 hr):combined = 4.9 mg/L; M = 5.8 mg/L & F = 4.0 mg/L	IV
870.2400	Primary Eye Irritation	41892703	Primary eye irritant - conjunctival redness in 1 hr. In al animals; persisted for 24 hrs. In 1/6 animals.	III
870.2500	Primary Skin Irritation	41892704	Negligible irritation in 0.5 hr. Cleared 24 - 48 hrs.	IV
870.2600	Dermal Sensitization	41892705	Not a sensitizer	

b. Toxic Effects and Carcinogenicity

The target organs following oral exposure to MMA (MSMA, DSMA, CAMA) are believed to be the gastrointestinal tract, particularly the large intestine, and the kidney. The target organs following oral exposure to DMA (cacodylic acid) are believed to be the bladder and thyroid.

MMA is classified as “no evidence for carcinogenicity” based on the lack of evidence of carcinogenicity in rats and mice. DMA is classified as “not carcinogenic up to doses resulting in regenerative proliferation.” Therefore, quantification of cancer risk is not required and a cancer analysis was not performed for MMA or DMA.

The metabolite inorganic arsenic is classified as a "human carcinogen;" therefore, quantification of cancer risk is required and a cancer analysis was performed for inorganic arsenic.

c. FQPA Considerations

The Food Quality Protection Act (FQPA) directs EPA, in setting pesticide tolerances, to use an additional tenfold (10x) margin of safety to take into account potential pre- and postnatal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. FQPA authorizes EPA to modify this tenfold safety factor only if reliable data demonstrate that the revised safety factor will be safe for infants and children.

Acceptable developmental studies in rats and rabbits along with a two-generation reproductive toxicity study are available for MMA. Results of developmental and reproductive toxicity studies provided no indication of increased susceptibility. The toxicology database is considered complete for the evaluation of sensitivity of the developing young. A developmental neurotoxicity study is not required. Toxicity to gastrointestinal tract and kidney provide the critical effects for MMA following oral exposures. These effects are more sensitive than toxicities noted in other studies, including developmental and reproductive toxicity and neurotoxicity. Therefore, the FQPA factor can be reduced to 1x. Further, EPA has adequate data and has included protective assumptions in its assessments to ensure that exposures are not underestimated.

Acceptable developmental studies in rats and rabbits along with a two-generation reproductive toxicity study are available for DMA. Results of developmental and reproductive toxicity studies provided no indication of increased susceptibility. The toxicology database is considered complete for the evaluation of sensitivity of the developing young. A developmental neurotoxicity study is not required. Regarding potential thyroid toxicity, a comparative thyroid study in adult and juvenile animals is not expected to provide endpoints more sensitive than the bladder mode of action studies currently available. The bladder is a sensitive target organ and special mode of action studies provide health protective endpoints for DMA toxicity at low doses. Thus, a comparative thyroid study in juvenile and adult animals is not required. Based on the overall weight of the evidence, the FQPA factor can be reduced to 1x.

d. Toxicological Endpoints

i. Organic Arsenic Toxicological Endpoints

The toxicological endpoints used in the human health risk assessment for MMA and DMA are presented in Table 7 and Table 8, respectively. The uncertainty and safety factors used to account for interspecies extrapolation, intraspecies variability, and for completeness of the data with respect to exposure and toxicity to infants and children (FQPA Safety Factor) are also presented in the tables below.

For acute and chronic exposure to MMA, EPA estimated risk using the traditional NOAEL approach. For chronic exposure to DMA, EPA estimated risk using a benchmark dose (BMD) approach. When available, BMDs are preferred over the NOAEL/LOAEL because BMDs generally more accurately identify the dose at which toxicological effects are observed. The NOAEL approach depends to an extent on the doses included in a study. Moreover, the NOAEL approach does not account for the uncertainty in the estimate of the dose-response. Benchmark dose analysis attempts to model the dose-response relationship with a dose-response curve that can be described by a mathematical function. The dose-response curve that is estimated based on the experimental observations is used to estimate the magnitude of the response for any dose within the experimental dose range.

Table 7. Summary of MMA Toxicological Endpoints

Exposure Scenario	Dose Used in Risk Assessment, UF	Level of Concern for Risk Assessment	Study and Toxicological Effects
Dietary Risk Assessment			
Acute Dietary (general population)	NOAEL = 10 mg/kg UF = 100 FQPA SF = 1	Acute RfD & PAD = 0.1 mg/kg	Chronic Toxicity in Dog, MMA study (MRID# 40546101) LOAEL = 40 mg/kg/day based on clinical signs of diarrhea and vomiting observed in the first of week of dosing with 2-5 hours of each days dosing.
Chronic Dietary (all populations)	NOAEL= 3.2 mg/kg/day UF = 100 FQPA SF = 1	Chronic RfD & PAD = 0.03 mg/kg/day	Chronic Toxicity Rat, MMA study (MRID# 41669001) Rat LOAEL = 27.2 mg/kg/day for males and 32.9 mg/kg/day for females based on decreased body weights, diarrhea, body weight gains, food consumption, histopathology of gastrointestinal tract and thyroid.
Occupational and Residential Risk Assessment			
Incidental Oral Short-Term (1 – 30 days)	NOAEL= 7 mg/kg/day FQPA SF = 1	LOC = 100	Rabbit developmental toxicity study (MRID# 15939001) LOAEL = 12 mg/kg/day, based on decreased body weight, food consumption (during the dosing period), and abortions.
Incidental Oral Intermediate-Term (1 - 6 months)	NOAEL= 3.2 mg/kg/day FQPA SF = 1	LOC = 100	Chronic Rat study (MRID# 41669001) LOAEL = 27.2 mg/kg/day for males and 32.9 mg/kg/day for females based on decreased body weights, diarrhea.
Dermal Short-Term (1 - 30 days) Intermediate-Term (1 - 6 months)	Dermal NOAEL= 1000 mg/kg/day FQPA SF = 1	LOC = 100	21-Day Dermal Toxicity in Rabbit, MMA study (MRID# 41872701) LOAEL > 1000 mg/kg/day.
Dermal Long-Term (> 6 months)	Not applicable		

Exposure Scenario	Dose Used in Risk Assessment, UF	Level of Concern for Risk Assessment	Study and Toxicological Effects
Inhalation Short-Term (1 - 30 days) Intermediate-Term (1 - 6 months)	Inhalation NOAEL= 0.01 mg/L (4.38 mg/kg/day, adjusted) FQPA SF = 1	LOC = 100	90-Day Inhalation with DMA - Rat (MRID# 44700301) LOAEL = 0.034 mg/kg/L (14.95 mg/kg/day) based on histopathology of nasal cells (i.e., presence of moderate and marked intracytoplasmic eosinophilic granules in nasal turbinate cells of male and female rats).
Cancer Classification			
"No evidence for carcinogenicity"			

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable

Table 8. Summary of DMA Toxicological Endpoints

Exposure Scenario	Dose Used in Risk Assessment, UF	Level of Concern for Risk Assessment	Study and Toxicological Effects
Dietary Risk Assessment			
Acute Dietary (females 13-49 and general population)	NOAEL = 12 mg/kg/day UF = 100 FQPA SF = 1	Acute RfD = 0.12 mg/kg/day	Developmental Toxicity - Rat (40625701) LOAEL = 36 mg/kg/day based on decreased fetal weights, shorter crown-rump length, the suggestion of diaphragmatic hernia and delayed/lack of ossification of numerous bones. Developmental Toxicity - Rabbit (40663301) LOAEL = 48 mg/kg/day based on mortality, abortions, body weight loss and reduced food consumption.
Chronic Dietary (all populations)	$BMDL_{10}$ = 0.43 mg/kg/day UF = 30[1] FQPA SF = 1	Chronic RfD = 0.014 mg/kg/day	BMD_{10} of 0.92 mg/kg/day based on regenerative proliferation of the bladder epithelial from Arnold et al (1999)

Exposure Scenario	Dose Used in Risk Assessment, UF	Level of Concern for Risk Assessment	Study and Toxicological Effects
Occupational and Residential Risk Assessment			
Incidental Oral Acute-Term (1 day)	NOAEL = 12 mg/kg/day FQPA SF = 1	LOC = 100	Developmental Toxicity - Rat (40625701) LOAEL = 36 mg/kg/day based on decreased fetal weights, shorter crown-rump length, the suggestion of diaphragmatic hernia and delayed/lack of ossification of numerous bones. Developmental Toxicity - Rabbit (40663301) LOAEL = 48 mg/kg/day based on mortality, abortions, body weight loss and reduced food consumption.
Incidental Oral Short-Term (1 - 30 days) Intermediate-Term (1 - 6 months)	$BMDL_{10}$ = 0.43 mg/kg/day FQPA SF = 1	LOC = 30	BMD_{10} of 0.92 mg/kg/day based on regenerative proliferation of the bladder epithelial from Arnold et al (1999)
Dermal Short-Term (1 - 30 days) Intermediate-Term (1 - 6 months)	Dermal NOAEL= 300 mg/kg/day FQPA SF = 1	LOC = 100	21-Day Dermal - Rabbit (41872801) LOAEL = 1000 mg/kg/day based on decreased body weight gain in females, and decreased testicular weights, hypospermia, and tubular hypoplasia in males.
Dermal Long-Term (> 6 months)	Not required		
Inhalation Short-Term (1 - 30 days) Intermediate-Term (1 - 6 months)	Inhalation NOAEL= 0.01 mg/L (4.38 mg/kg/day, adjusted) FQPA SF = 1	LOC = 100	90-Day Inhalation - Rat (44700301) LOAEL = 0.034 mg/kg/L (14.95 mg/kg/day) based on presence of moderate and marked intracytoplasmic eosinophilic granules (IEG) in the nasal turbinate cells of male and female rats.
Inhalation Long-Term (> 6 months)	Not required		
Cancer Classification			
"Not carcinogenic at doses that do not result in enhanced cell proliferation"			

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable
[1] The database supports reduction of the default 10x inter-species extrapolation to 3x for chronic dietary exposure. The key events of the rat bladder tumor mode of action are expected to be operational in humans

and it is further expected that at a similar dose at the target site (i.e., bladder urothelial) humans and rats will respond in a pharmacodynamically similar way. In the December 2005 draft SAB report, the panel provides support for reducing the default 10x interspecies factor to "some number less than 10" and that the "EPA could assemble a case for toxicodynamic equivalency between the test species, rats, and humans from existing experimental data."

ii. Inorganic Arsenic Toxicological Endpoints

Inorganic arsenic is classified as a "human carcinogen;" therefore, quantification of cancer risk is required and a cancer analysis was performed. Epidemiological data show that increased lung cancer mortality was observed in multiple human populations exposed primarily through inhalation. Also, increased mortality from multiple internal organ cancers (liver, kidney, lung, and bladder) and an increased incidence of skin cancer were observed in populations consuming drinking water high in inorganic arsenic.

EPA estimates lifetime cancer risk using the estimated exposure and the carcinogenic potential of the compound (Q_1* or cancer slope factor). The risk is expressed as a probability of developing cancer (e.g., one-in-a-million or 1×10^{-6}). To evaluate potential lifetime cancer risk resulting from exposure to inorganic arsenic in drinking water, EPA estimated the inorganic arsenic exposure resulting from pesticidal uses and compared the estimated risk to EPA's LOC.

To derive the LOC, EPA used the cancer slope factor for inorganic arsenic to calculate the exposure level in drinking water (expressed as ppb) that would be below 1×10^{-6} excess cancer risk. For this risk assessment, an oral cancer slope factor of 3.67 $(mg/kg/day)^{-1}$ was used. This value is based on the Agency's risk assessment associated with inorganic arsenic in drinking water presented in 2000. It is consistent with the slope factor used by the EPA Office of Water for the arsenic maximum contaminant level (MCL) and in OPP's 2003 Draft Preliminary Report entitled, "A Probabilistic Risk Assessment for Children Who Contact CCA-Treated Playsets and Decks." Based on the 3.67 $(mg/kg/day)^{-1}$ cancer slope factor, OPP's level of concern for exposure to inorganic arsenic in drinking water is equivalent to 0.02 ppb or one-in-a-million (1×10^{-6}) excess cancer risk.

2. Dietary Exposure and Risk from Food and Drinking Water

Because arsenic is ubiquitous and exists in many forms in the environment, it is difficult to quantify the extent to which measured arsenic is organic versus inorganic and the extent to which measured arsenic – whether organic, inorganic, or total – is present due to organic arsenic herbicide use versus naturally occurring (i.e., background levels). Because of the complexities of separating or "speciating" arsenic in food and drinking water and the differences in toxicity, EPA conservatively estimated dietary risk assuming that 100% of the exposure could be to organic arsenic or inorganic arsenic. These estimates may overestimate organic arsenic or inorganic arsenic exposure and risk because the exposure is known to be to a combination of organic and inorganic arsenic compounds.

EPA's organic arsenic dietary risk assessment estimates acute (single-day) and chronic (lifetime) toxicity to humans from ingesting a pesticide through food and drinking water sources. Because MMA (MSMA, DSMA, CAMA) and DMA (cacodylic acid) are not carcinogens at exposure levels expected in humans, EPA estimated acute and chronic non-cancer dietary risk. Non-cancer dietary risk is expressed as a percentage of a level of concern. The level of concern is the dose at or below which no unreasonable adverse health effects to any human population subgroup are expected to occur. This dietary level of concern is termed the population adjusted dose (PAD), which reflects the reference dose (RfD), either acute or chronic, adjusted for (divided by) the FQPA safety factor. Estimated risks that are less than 100% of the PAD are below EPA's level of concern. The acute PAD (aPAD) is the highest predicted dose to which a person could be exposed on a single day with no expected adverse health effect. The chronic PAD (cPAD) is the highest predicted dose to which a person could be exposed over the course of a lifetime with no expected adverse health effect.

Because inorganic arsenic is a known human carcinogen, EPA estimated cancer risk from dietary exposure to the inorganic arsenic alone that could result from pesticide uses alone. EPA's inorganic arsenic dietary risk assessment first estimates lifetime cancer risk to humans from ingesting the inorganic arsenic metabolite through drinking water sources. Since drinking water exposure alone is problematic, food sources have not been included, but would be expected to increase risk concerns. Lifetime cancer risk is estimated using the exposure and cancer potency factor (Q_1*) and is expressed as a probability of developing cancer. Cancer risks greater than one-in-a-million (1×10^{-6}) exceed OPP's level of concern.

a. Organic Arsenic Dietary Exposure and Risk

To estimate organic arsenic dietary exposure, EPA made the conservative assumption that 100% of the exposure could be to organic arsenic. These estimates may overestimate organic arsenic exposure and risk because the exposure is known to be to a combination of organic and inorganic arsenic compounds.

Additionally, the Food Quality Protection Act of 1996 requires EPA to consider the dietary exposure from all sources of a pesticide or, in this case, organic arsenic. "All sources of organic arsenic" includes background (naturally occurring) levels of organic arsenic in food and drinking water that are not necessarily resulting from the pesticidal uses. To assess dietary exposure resulting from the pesticidal uses only, as well as to consider all sources of organic arsenic that contribute to dietary exposure, EPA performed three levels of dietary analyses using field trial data, modeled drinking water exposure estimates, and the US Food and Drug Administration (FDA) Total Diet Study (TDS). Level 1 most likely represents residues in food and water as a result of organic arsenical herbicide applications. The Level 2 and Level 3 analyses include increasingly broad exposure assumptions and were used to estimate aggregate dietary exposure to arsenic from all potential sources.

Level 1: Pesticide applications only (no background)
The level 1 acute and chronic dietary exposure analyses include cottonseed, the only registered food commodity (residue estimates from field trial data), and two different water scenarios reflecting uses on cotton and on turf. All residues are considered to be either MMA or DMA.

Level 2: Pesticide applications plus residues in meat and fish
The level 2 acute and chronic dietary exposure analyses include: a) cottonseed and meat (residue estimates from FDA TDS); b) cottonseed, meat, and two different water scenarios; c) cottonseed, meat, and fish (residue estimates from FDA TDS); and, d) cottonseed, meat, fish, and two different water scenarios. All residues are considered to be either MMA or DMA.

Level 3: Pesticide applications plus background arsenic levels in food
The level 3 acute and chronic dietary exposure analyses include: a) cottonseed and all commodities that were tested in the FDA TDS; b) cottonseed, all commodities that were tested in the FDA TDS (e.g., cooked rice, cereal) and two different water scenarios; c) cottonseed, all commodities that were tested in the FDA TDS, as well as all commodities to which those data could be translated; and, d) cottonseed, all commodities that were tested in the FDA TDS, all translated commodities, and two different water scenarios. All residues are considered to be either MMA or DMA.

This document includes only the results of the Level 3 analysis because it represents a very conservative "worst-case" dietary exposure scenario and the estimated risks do not exceed EPA's level of concern. Results of the Level 1 and Level 2 analyses are available at http://www.regulations.gov in docket number EPA-HQ-OPP-2006-0201.

i. MMA Acute and Chronic Dietary Risk

The acute and chronic results of the Level 3 dietary analyses are presented in Table 9 and Table 10, respectively, and assume 100% of the total arsenic concentration is MMA. The acute dietary risk estimates at the 99.9th percentile for food and water aggregate exposure to MMA are below EPA's level of concern for the U.S. population and all population subgroups. Results of the Level 1 and Level 2 analyses are not presented in this document because the Level 3 analysis presents a "worst-case" scenario and still does not exceed EPA's level of concern.

Table 9. Summary of MMA Level 3 Acute Dietary Risk

Population Subgroup	Food only		Food + Cotton Water		Food + Turf Water	
	Exposure (mg/kg/day)	%aPAD	Exposure (mg/kg/day)	%aPAD	Exposure (mg/kg/day)	%aPAD
U.S. Population	0.036201	36.2	0.036779	36.8	0.047609	47.6
All Infants (<1 yr.)	0.028218	29.2	0.031956	31.2	0.089358	89.4
Children 1-2 yrs.	0.067527	67.5	0.068276	68.3	0.073761	73.8

Table 10. Summary of MMA Level 3 Chronic Dietary Risk

Population Subgroup	Food only		Food + Cotton Water		Food + Turf Water	
	Exposure (mg/kg/day)	% cPAD	Exposure (mg/kg/day)	% cPAD	Exposure (mg/kg/day)	% cPAD
U.S. Population	0.000795	2.6	0.001027	3.4	0.003493	11.6
All Infants (<1 yr.)	0.000611	2.0	0.001371	4.6	0.009456	31.5
Children 1-2 yrs.	0.001828	6.1	0.002172	7.2	0.005835	19.4

ii. DMA Acute and Chronic Dietary Risk

The acute and chronic results of the Level 3 analyses are presented in Table 11 and Table 12, respectively, and assume 100% of the total arsenic concentration is DMA. The acute dietary risk estimates at the 99.9th percentile for food and water aggregate exposure to DMA are below EPA's level of concern for the U.S. population and all population subgroups. Results of the Level 1 and Level 2 analyses are not presented in this document because the Level 3 analysis presents a "worst-case" scenario and does not exceed EPA's level of concern.

Table 11. Summary of DMA Level 3 Acute Dietary Risk

Population Subgroup	Food only		Food + Cotton Water		Food + Turf Water	
	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	%aPAD
U.S. Population	0.036201	30.2	0.036537	30.4	0.038003	31.7
Children 1-2 yrs.	0.067527	56.3	0.067877	56.6	0.069642	58.0

Table 12. Summary of DMA Level 3 Chronic Dietary Risk

Population Subgroup	Food only		Food + Cotton Water		Food + Turf Water	
	Exposure (mg/kg/day)	% cPAD	Exposure (mg/kg/day)	% cPAD	Exposure (mg/kg/day)	% cPAD
U.S. Population	0.000795	5.7	0.000942	6.7	0.001764	12.6
All Infants (<1 yr.)	0.000611	4.4	0.001094	7.8	0.003790	27.1
Children 1-2 yrs.	0.001828	13.1	0.002047	14.6	0.003268	23.3

b. Inorganic Arsenic Dietary Risk

To estimate inorganic arsenic dietary exposure, EPA made the conservative assumption that 100% of the exposure could be to inorganic arsenic. These estimates may overestimate inorganic arsenic exposure and risk because the exposure is known to be to a combination of organic and inorganic arsenic compounds; however, limited monitoring data in areas with high organic arsenical herbicide use appear to support a relatively high level of transformation and thus confirm EPA's risk conclusions.

EPA estimated dietary risk to inorganic arsenic resulting from the organic arsenical herbicide uses based on estimated drinking water exposure alone (i.e., without food or background levels of arsenic). Cancer risk was calculated based on potential long term EDWCs predicted using surface water modeling and using EPA's Q_1* for inorganic arsenic. The resulting dietary exposure exceeds OPP's 1 x 10^{-6} excess cancer risk (Table 13). EPA did not combine the EDWCs with food exposure because the risks posed by EDWCs alone are above the LOC and further combination would result in increased risk estimates that would further exceed the LOC.

Table 13. Inorganic Arsenic Surface Water EDWCs and Corresponding Cancer Risks

COTTON		**TURF**	
Total Arsenic Cancer EDWC	**Cancer Risk**	**Total Arsenic Cancer EDWC**	**Cancer Risk**
3.9 ppb	3 x 10^{-4}	40.3 ppb	3 x 10^{-3}

Note: OPP's target cancer risk is 1 x 10^{-6} equivalent to 0.02 ppb of inorganic arsenic

The modeled surface water EDWCs are intended to provide high end estimates of potential drinking water exposure, representing exposure that might be expected in worst-case scenarios when maximum labeled rates are applied in the most vulnerable sites. This exposure may not have widespread occurrence nationally, depending on the extent of vulnerability. Additional conservative assumptions are included in modeling exposure from the turf use, leading to turf EDWCs that may be overestimated to some degree, although the extent of overestimation cannot be quantified. Although there are uncertainties in the modeling, available monitoring data support the conclusion that typical use of organic arsenicals may result in drinking water exposure to inorganic arsenic that exceeds levels of concern.

For surface water, a US Geological Survey study at river sites downstream of high cotton use areas in Mississippi monitored for organic and inorganic arsenic, finding both at concentrations up to 5 ppb. These detections are higher than background levels in the study area which are not expected to exceed 2 ppb for total arsenic, with limited natural contribution to organic arsenic levels.

Several monitoring studies in Florida golf course ponds found total arsenic concentrations in individual samples of up to 120 ppb with annual means at individual ponds of up to 64 ppb. Background arsenic in Florida surface water is expected to be <2 ppb. One of these studies speciated the total arsenic detections and found that in all but a few samples, inorganic arsenic was dominant, representing more than 60% of the total arsenic in most cases with many samples made up entirely of inorganic arsenic. This indicates that significant transformation of organic arsenic to inorganic arsenic had occurred. While these concentrations are not directly comparable to levels of exposure in drinking water, they demonstrate that organic arsenical herbicide applications can result in substantial transport of organic and inorganic arsenic to surface water.

Groundwater may also be susceptible to arsenic contamination through leaching of applied organic arsenical herbicides. Areas with shallow water tables, well drained soils, and low background arsenic levels are particularly vulnerable to impacts from organic arsenical herbicide use. Although modeling of potential groundwater exposure was not conducted, available monitoring data show that in these environments, groundwater may be impacted by organic arsenical use. In Florida, a vulnerable environment, 90% of the state's drinking water comes from groundwater. From 2003 to 2005, at least 5% of Florida drinking water compliance monitoring samples exceeded 3 ppb arsenic with detections as high as 240 ppb. These detections are not directly linked to organic arsenical herbicide use, but they exceed typical background values and are likely impacted by some kind of anthropogenic input (e.g., organic arsenical herbicides). Monitoring in shallow wells beneath golf courses detected arsenic in groundwater at 9 of 14 Florida golf courses tested, with detections of up to 120 ppb in shallow wells (<12 ft depth) and up to 11 ppb in deeper wells (<28 ft depth).

Considering both the modeling results and the monitoring data, the weight of the evidence supports EPA's conclusion that use of organic arsenical herbicides may lead to exposure to inorganic arsenic in drinking water that exceeds levels of concern for excess cancer risk.

3. Residential Exposure and Risk

a. Organic Arsenic Residential Risk

MSMA, DSMA, CAMA, and cacodylic acid are currently registered for use in residential settings. Non-cancer risk estimates (such as residential estimates) are expressed as a margin of exposure (MOE) which is a ratio of the dose from a toxicological study selected for risk assessment, typically a NOAEL, to the predicted exposure. Estimated MOEs are compared to a level of concern which reflects the dose selected for risk assessment and uncertainty factors (UF) applied to that dose. The standard UF is 100x, which includes 10x for interspecies extrapolation (to account for differences between laboratory animals and humans) and 10x for intraspecies variation (to account for differences within the same species). Additional uncertainty or safety factors may also be applied.

There are potential exposures to residential handlers (mixers, loaders, and applicators) during the usual use-patterns associated with MSMA, DSMA, CAMA, and cacodylic acid. All risks for residential handlers are below EPA's level of concern (MOE 140 to 29,000 for dermal; MOE 4,700 to 320,000 for inhalation).

There are potential exposures to individuals in residential settings following application of MSMA, DSMA, CAMA, and cacodylic acid. The following postapplication scenarios were identified:

- dermal exposure from residues on lawns (adult and toddler);
- hand-to-mouth transfer of residues on lawns (toddler);
- ingestion of pesticide residue on treated grass (toddler); and
- incidental ingestion of soil from pesticide-treated residential areas (toddler).

There are potential postapplication risks of concern for MSMA, DSMA, CAMA, and cacodylic acid as they are currently used in residential settings. The target level of concern for DMA incidental oral scenarios is 30 (i.e., MOE $\geq$ 30 is not of concern). Table 14 presents the short-term incidental oral MOEs for DMA for toddlers that are <30 for the hand-to-mouth activity and object-to-mouth activities on turf.

Table 14. Toddler Residential Risks of Concern for Postapplication Exposure to DMA

Exposure Scenario	Route of Exposure	Formulation	Application Rate (lb ai/A)	MOE -- Day 0
Hand to Mouth Activity on Turf	Oral	Spray	7.72	4
			7.3	4
Object to Mouth Activity on Turf			7.72	15
			7.3	16

b. Inorganic Arsenic Residential Risk

The estimated residential exposure to inorganic arsenic is small compared to the estimated exposure in drinking water. EPA believes the residential exposure would primarily be to organic arsenic during application or shortly after application. Transformation of the organic arsenic to inorganic arsenic would occur over time and buildup in soil of the inorganic form is possible. Although inorganic arsenic levels in soil may increase, exposure over time would be low since the inorganic material would be below the soil surface and not be readily available for exposure. The main route of exposure to inorganic arsenic would be thru the ingestion of treated soil, but EPA does not believe this is a major route of long term exposure. EPA did not combine the EDWCs with food or residential exposure because the risks posed by EDWCs alone are above the LOC and further combination would result in increased risk estimates that would further exceed the LOC.

4. Aggregate Risk

In reassessing tolerances, FFDCA Section 408(b)(2)(A)(ii) requires EPA to examine the "aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposure and other exposures for which there is reliable information." An aggregate risk assessment considers the combined risk from dietary exposure (food and drinking water) as well as exposure from non-occupational sources (residential uses).

a. Acute Aggregate Risk for Organic Arsenic

Acute aggregate exposures (less than one day) may result from consuming treated food or drinking water. Acute aggregate exposures may also result from residential exposures such as adults doing yard work or playing golf on treated turf, or from children playing on treated turf. Typically EPA does not aggregate acute dietary exposures with acute residential exposures because it is very unlikely that high-end food and water exposures will occur on the same day as the maximum residential exposures. Therefore, acute aggregate risks for MMA and DMA are considered to represent the acute dietary risks. As noted above, the acute dietary risk estimates for the U.S. population and all subgroups are well below EPA's level of concern. The most highly exposed subgroup for MMA is all infants (<1 yr.) at 89.4% of the aPAD and the most highly exposed subgroup for DMA is children 1-2 at 58.0% of the aPAD.

b. Short-Term Aggregate Risk for Organic Arsenic

Aggregate short-term risk estimates include the contribution to risk from chronic dietary sources (food + water) and short-term residential or recreational sources. Though estimated aggregate chronic (long-term) dietary risks are not of concern, short-term residential exposures alone pose potential risks of concern to toddlers from postapplication exposures to DMA and CAMA. EPA did not aggregate residential exposure with dietary exposure because the risks posed by residential exposure alone are above the LOC and further aggregation would result in increased risk estimates that would further exceed the LOC. Residential risks from CAMA could likely be addressed through mitigation (e.g., relatively small rate reductions). However, risks from DMA would necessitate much more extensive mitigation.

EPA combines risk values resulting from separate residential postapplication exposure scenarios when it is likely they can occur simultaneously based on the use-pattern and the behavior associated with the exposed population. The combined MOEs for MSMA and DSMA do not exceed EPA's level of concern; the combined MOEs for CAMA at the 4.4 lbs. ai/A rate and cacodylic acid at the 7.3 and 7.7 lbs. ai/A rates exceed EPA's level of concern and are presented in Table 15 and Table 16, respectively.

Table 15. Combined MOE Estimates for CAMA

Postapplication Exposure Scenario			**Margins of Exposure (MOEs) (UF=100)**	
			Short-Term (Non-Dietary)	**Total Non-Dietary Risk**
Turf				
Toddler	Turf (4.4 lb ai/acre)	Hand to Mouth	110	85
		Object to Mouth	430	
		Incidental Soil Ingestion	32,000	

Postapplication Exposure Scenario			Margins of Exposure (MOEs) (UF=100)	
			Short-Term (Non-Dietary)	Total Non-Dietary Risk
	Turf (3.7 lb ai/acre)	Hand to Mouth	130	101
		Object to Mouth	510	
		Incidental Soil Ingestion	38,000	
	Turf (2.2 lb ai/acre)	Hand to Mouth	210	170
		Object to Mouth	850	
		Incidental Soil Ingestion	64,000	

Table 16. Combined Toddler MOE Estimates for DMA

Postapplication Exposure Scenario			Margins of Exposure (MOEs) (UF=30)	
			Short-Term (Non-Dietary)	Total Non-Dietary Risk
Turf				
Toddler	Turf (7.72 lb ai/acre)	Hand to Mouth	4	3
		Object to Mouth	15	
		Incidental Soil Ingestion	1,100	
	Turf (7.3 lb ai/acre)	Hand to Mouth	4	3
		Object to Mouth	16	
		Incidental Soil Ingestion	1,200	

c. Intermediate-Term Aggregate Risk for Organic Arsenic

All residential/recreational exposures are expected to be short-term in duration; therefore, no intermediate-term aggregate analysis was performed.

d. Long-Term Aggregate Risk for Organic Arsenic

Long-term (noncancer) aggregate risk estimates include the contribution of risk from chronic dietary sources (food + water) and residential sources. However, based on the labeled uses, no long-term or chronic residential exposures are expected. Chronic risk estimates from exposures to food alone do not exceed EPA’s level of concern for any exposed population or subgroup based on conservative estimates of exposure. As in the acute aggregate assessment, chronic surface water EDWCs were calculated to estimate the potential contribution to the chronic exposure from drinking water, and the EDWCs were combined with chronic food exposures to estimate potential long-term aggregate risks from the uses of DMA and MMA. Aggregate chronic dietary exposure did not exceed EPA's level of concern for MMA (32% of the cPAD for the highest exposed subgroup, infants <1 yr.) or DMA (27% of the cPAD for the highest exposed subgroup, infants <1 yr.).

e. Aggregate Cancer Risk for Organic Arsenic

MMA is classified as "no evidence for carcinogenicity," based on the lack of evidence of carcinogenicity in acceptable studies in rats and mice. DMA is classified as "not carcinogenic up to doses resulting in regenerative proliferation," therefore a cancer dietary analysis was not warranted and was not performed.

f. Aggregate Cancer Risk for Inorganic Arsenic

Inorganic arsenic is classified as a "known human carcinogen;" therefore, a cancer assessment was performed. EPA estimated dietary cancer risk to inorganic arsenic resulting from the organic arsenical herbicide uses by calculating the estimated drinking water exposure alone (i.e., without food or background levels of arsenic) using EPA's cancer potency factor (Q_1*) for inorganic arsenic. The resulting dietary exposure exceeds OPP's 1×10^{-6} excess cancer risk (3×10^{-3} for turf uses). EPA did not aggregate the EDWCs with food, residential, or background exposure because the risks posed by EDWCs alone are above the LOC and further aggregation would result in increased risk estimates that would further exceed the LOC.

5. Cumulative Risk Assessment

Risks summarized in this document are those that result only from the use of the organic arsenical herbicides. The Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to the organic arsenical herbicides. EPA has not assumed that the organic arsenical herbicides share a common mechanism of toxicity with other compounds. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism of toxicity on EPA's website at http://www.epa.gov/pesticides/cumulative/.

6. Occupational Risk

a. Organic Arsenic Occupational Risk

Workers can be exposed to MSMA, DSMA, CAMA, or cacodylic acid by mixing, loading, or applying or by entering a previously treated site. Like residential risk, worker risk is measured by MOEs. For handlers, EPA initially assesses risk at "baseline" which considers normal work clothing (i.e., long sleeve shirt and long pants), no gloves, and no respirator. If there is a concern at baseline, EPA considers the use of protective measures (e.g., personal protective equipment) to lower the risk. Personal protective equipment (PPE) can include an additional layer of clothing, chemical-resistant gloves, and/or a respirator.

i. Organic Arsenic Occupational Handler Risk

Occupational handlers can be exposed to MMA or DMA by mixing, loading, or applying MSMA, DSMA, CAMA, or cacodylic acid.

For inhalation exposure, all scenarios for MSMA, DSMA, and CAMA do not exceed EPA's level of concern at baseline. For dermal exposure, several scenarios exceed EPA's level of concern for MSMA (MOEs = 12 to 89), DSMA (MOEs = 12 to 90), and CAMA (MOEs = 55 to 66) at baseline. All scenarios are below EPA's level of concern at baseline plus gloves (MOEs = 580 to 66,000).

For inhalation exposure, all scenarios for cacodylic acid do not exceed EPA's level of concern at baseline. For dermal exposure, several scenarios exceed EPA's level of concern for cacodylic acid (MOEs = 7.5 to 56). All but one scenario (MOE = 92) was below EPA's level of concern at baseline plus gloves (MOEs = 580 to 66,000).

ii. Organic Arsenic Occupational Postapplication Risk

Workers can be exposed to MMA or DMA by being in an environment that has been previously treated with MSMA, DSMA, CAMA, or cacodylic acid.

For inhalation and dermal exposures, all scenarios for MSMA, DSMA, and CAMA do not exceed EPA's level of concern at baseline assuming workers do not enter before the 12-hour restricted entry interval (REI).

For inhalation exposures, all scenarios for cacodylic acid do not exceed EPA's level of concern at baseline assuming workers do not enter before the 12-hour REI. For dermal exposures, several scenarios for cacodylic acid exceed EPA's level of concern at baseline as presented in Table 17. Post application risk would likely be of greatest concern for workers on sodfarms and could be addressed with longer REIs.

Table 17. Postapplication Worker Risks of Concern for Cacodylic Acid

Crop Grouping	Application rate (lb ai/acre)	Transfer Coefficient	Day after Application when MOE ≥100	MOE at Day 0
Turf	7.7	3400	8	45
		6800	14	22
	7.3	3400	7	47
		6800	13	24

b. Inorganic Arsenic Occupational Risk

Mixers and loaders, and most post-application workers would only be exposed to organic arsenic. The estimated occupational exposure to inorganic arsenic from application of MSMA, DSMA, CAMA or cacodylic acid products is insignificant. Thus, no quantitative estimate has been completed.

7. Incident Reports

There are reported MSMA and DSMA incidents involving adults and children, several of which resulted in hospitalization. Some reports described symptoms such as dizziness, sinusitis, rhinitis, memory loss, numbness, tingling, rash, and fever, after aerial applications, but many were non-specific about the source of exposure. Other reports described effects such as systemic allergic symptoms, nausea, dizziness, and eye irritation for both agricultural and non-agricultural uses. From the limited information available, systemic allergic reactions and eye irritation are the most common types of effects seen.

EPA had no reported incidents for CAMA.

There are reported cacodylic acid incidents involving children < 6 years of age, but none resulted in hospitalization. No other information, such as the activity associated with the exposure, was reported. Incidents reported for adults involved both agricultural and non-agricultural uses and included skin and eye irritation, respiratory effects, and systemic effects. The incidents resulted in absences from work and, in a few cases, hospitalization. Incidents were associated with use on lawn, turf, ornamentals, and cotton.

C. Environmental Risk Assessment

EPA has conducted an environmental risk assessment for the organic arsenical herbicides to support the reregistration eligibility decision. EPA evaluated the submitted environmental fate and ecological studies as well as available open literature and determined that the data are adequate to support a reregistration eligibility decision. A summary of the environmental risk assessment findings and conclusions is provided below; the full risk assessments are available at http://www.regulations.gov in docket number EPA-HQ-OPP-2006-0201.

1. Environmental Fate and Transport

Unlike other pesticides that degrade over time, MSMA, DSMA, CAMA, and cacodylic acid contain the element arsenic which does not degrade. Arsenic can, however, transform (i.e., change forms) or be redistributed through runoff, leaching, erosion, volatilization, or plant uptake. The extent and speed of transformation and redistribution of the organic arsenical herbicides in soil is highly variable and depends mostly on localized environmental conditions. Thus, persistence of applied organic arsenical herbicides can range from days to years, depending on soil properties and ambient conditions such as soil moisture, temperature, chemical concentration, bacterial population, and amount of organic matter.

Although the environmental fate of the organic herbicides is highly variable depending on localized environmental conditions, environmental fate laboratory studies show that organic arsenicals are stable under all tested abiotic conditions; they do not degrade by hydrolysis or by aquatic or soil photolysis. Metabolism rates do not appear to depend linearly on arsenical concentration; the kinetics are therefore not necessarily first-order and so “half-life” may not be an appropriate constant for all concentrations. Despite the uncertainty, first-order half-lives have been calculated for modeling purposes. The estimated half-lives used in the risk assessments may underestimate the faster initial rate of metabolism but adequately portray the overall transformation and so are assumed to be protective for chronic exposure, a major concern for arsenicals.

The modeled aerobic and anaerobic soil half-lives for MMA and DMA are presented in Table 18. The modeled aerobic soil half-life for MMA is 240 days; no anaerobic soil half-life was determined. The modeled aerobic soil half-life for DMA is 173 ± 115 days with a standard upper 90% confidence limit on the mean of 240 days. The anaerobic soil half-life for DMA was calculated to be 128 ± 38 days with a standard upper 90% confidence limit on the mean of 168 days.

Table 18. Soil Half-Lives for MMA and DMA used in EPA’s Risk Assessments

Chemical	Aerobic Half-Life	Anaerobic Half-Life
MMA	240 days	ND
DMA	173 ± 115 days	128 ± 38 days

ND = Not determined

The effects of environmental factors on the rate of arsenical metabolism are complex and poorly defined, with different studies leading to conflicting results. An increase in temperature leads to increased metabolism. The observed influences of soil organic matter or applied arsenical concentrations are contradictory. The effect of aerobic versus anaerobic conditions on metabolism rates is also ambiguous.

a. Metabolites

Potential metabolites of applied organic arsenicals include volatile alkylarsines and inorganic arsenic (as arsenate or arsenite) along with carbon dioxide. Additionally, DMA may be present as a metabolite of MMA as well as applied directly. As with the rate, the metabolism pathway is sensitive to environmental conditions in indeterminate ways with the major metabolites occurring in widely variable proportions. Transformation to volatile alkylarsines, the only metabolism route that would directly reduce soil arsenic loading, has been shown to be possible in certain circumstances but is generally not expected to be a major route of dissipation. A maximum of 35% of applied MMA is expected to be present as DMA at any one time. Theoretically, there is some possibility for MMA to metabolize to DMA, but significant transformation has not been observed in current acceptable field or laboratory studies. Observed metabolism of MMA and DMA to inorganic arsenic has ranged from undetected after several years to more than 80% transformation in several months. Generally, arsenate [As(V)] is expected to be the dominant species of inorganic arsenic, but in reducing conditions, arsenite [As(III)] may be more stable.

Some of the variability in metabolism processes is associated with variability in sorption, because microbial transformation is only likely to occur while compounds remain dissolved in pore water. Mobility of arsenicals is typically very low to intermediate and appears to be independent of organic matter content. Instead, sorption is higher in soils with higher percentage of clay or with more iron or aluminum content. One study found by direct comparison that all arsenicals were more strongly sorbed than phosphate in the increasing order: phosphate < DMA < arsenate ~ MMA. The lowest non-sand K_d for MMA is 11.4 mL/g. For 20 tested soils, the range of K_ds spans two orders of magnitude (0.5 to 95 mL/g, mean 37 mL/g). For DMA, the lowest non-sand K_d from 16 soils is 8.2 mL/g (range 8.2 to 33 mL/g, mean 18 mL/g).

b. Surface Water Exposure Conclusions

Arsenical pesticides and their metabolites may be transported to surface waters and sediments through runoff water, eroding soils, or drift during application. These routes of exposure are likely to lead to elevations above background arsenic levels in surface water bodies. Tier I surface water modeling for MSMA and DSMA estimated surface water concentrations in ponds and streams as high as 360 ppb, as MMA. Limited targeted monitoring has found elevated total arsenic levels in surface water bodies in MMA use areas. In cotton growing areas in Mississippi, surface water concentrations of MMA up to 5 ppb were detected. In Florida, concentrations of up to 120 ppb have been detected in golf course ponds.

c. Soil Accumulation Conclusions

The relative immobility of arsenicals along with arsenic's elemental nature make buildup in soil after repeated applications an important consideration. Controlled field studies, monitoring targeted to pesticide use areas, and soil modeling results all indicate that soil buildup is a likely result of long term organic arsenical application. Arsenic accumulation is likely to be limited to the top layers of soil, with studies suggesting that it is unlikely to occur at depths greater than 30 cm.

2. Environmental Effects

a. Ecological Risk Estimation

EPA's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations (EECs) based on environmental fate characteristics and pesticide use data. To evaluate the potential risk to non-target organisms from the use of organic arsenic herbicide products, the Agency calculated a Risk Quotient (RQ), which is the ratio of the EEC to the most sensitive toxicity endpoint value, such as the median lethal dose (LD_{50}) or the median lethal concentration (LC_{50}). These RQ values are then compared to EPA's level of concern (LOC) indicating whether or not a pesticide, when used as labeled, has the potential to cause adverse effects on non-target organisms. If an RQ exceeds the LOC, the risk may be addressed through further refinements of the assessment or through mitigation. Use, toxicity, fate, and exposure are considered when characterizing the risk, as well as the levels of certainty and uncertainty in the assessment. EPA further characterizes ecological risk based on any reported incidents to non-target terrestrial or aquatic organisms in the field (e.g., fish or bird kills). Table 19 presents EPA's level of concern for acute, acute endangered listed species, and chronic risk for terrestrial and aquatic animals as well as plants.

Table 19. Target Levels of Concern for Ecological Risk Assessments

Risk Category	Terrestrial Animal LOC	Aquatic Animal LOC	Plant LOC
Acute Risk	0.5	0.5	1
Acute Endangered Listed Species	0.1	0.05	1
Chronic Risk	1	1	Not Assessed

b. Aquatic Organism Risk

All calculated MMA and DMA RQs for fish and aquatic invertebrates are < 0.05 and below EPA's level of concern (LOC). All calculated MMA and DMA RQs for aquatic plants are < 1 and below EPA's level of concern (LOC).

c. Terrestrial Organism Risk

Most of the terrestrial mammal acute RQs for exposure to MMA or DMA, except those for granivores, exceeded the endangered species LOC of 0.1; some also exceeded the restricted use LOC of 0.2 and high risk LOC of 0.5. These RQs are presented below in Table 20 for MMA and Table 21 for DMA. All but 2 of the chronic RQs for MMA exceeded the chronic risk LOC of 1. For DMA, chronic RQs were not calculated but there is evidence that chronic exposure may be toxic to some mammals, based on the results of a developmental rabbit study in which the toxic threshold was below the estimated exposure. These RQs are calculated based on mammals with body weights of 35 g that consume green vegetation or insects equivalent to 66% of their body weight (herbivores and insectivores) or seeds equivalent to 15% of their body weight (granivores).

Table 20. Risk Quotients for Small Mammals (35g) Exposed to MMA

Crop (Chemical)	**Acute RQs [1]**			**Chronic RQs [2]**		
	Herbivore	**Insectivore**	**Granivore**	**Herbivore**	**Insectivore**	**Granivore**
Cotton	0.17*	0.10*	<0.1	7.3‡	4.1‡	0.46
Non-crop	6.04***	3.39***	<0.1	26‡	14‡	1.6‡
Orchard	0.48**	0.27**	<0.1	21‡	12‡	1.3‡
Turf; max	5.25***	2.95***	<0.1	22‡	13‡	1.4‡
Turf; golf	3.50***	1.97***	<0.1	15‡	8.3‡	0.93

[1] Acute RQ = EEC / LD50, corrected for body weight; LD50s = 1599 mg/kg (rat) for DSMA, 157 mg/kg (rat) for MSMA, adjusted for purity of test material.
[2] Chronic RQ = EEC/NOEC, corrected for body weight; NOEC = 100 ppm (rat) for MMA
*** exceeds LOCs for high risk (0.5), restricted use (0.2), and endangered species (0.1)
** exceeds the LOCs for restricted use and endangered species
* exceeds the LOC for endangered species
‡ exceeds the chronic risk LOC (1)

Table 21. Risk Quotients for Small Mammals (35g) Exposed to DMA

Crop (Chemical)	**Acute RQs [1, 2]**			**Chronic RQs**		
	Herbivore[3]	**Insectivore[3]**	**Granivore[4]**	**Herbivore**	**Insectivore**	**Granivore**
Cotton	0.2**	0.1*	<0.1	Not quantified		
Noncrop Areas	1.6***	1.9***	<0.1			
Orchards (understory)	1.0***	1.2***	<0.1			

[1] RQ = EEC / [LD50 / food eaten expressed as % of bw]
[2] LD50 = 823 mg/kg (lab. rat)
[3] for a 35-g herbivore or insectivore (mammal) that consumes an amount of green vegetation or insects equivalent to 66% of its body weight
[4] for a 35-g granivore (mammal) that consumes an amount of seeds equivalent to 15% of its body weight
*** exceeds LOCs for high risk (0.5), restricted use (0.2), and endangered species (0.1)
** exceeds the LOCs for restricted use and endangered species
* exceeds the LOC for endangered species
‡ exceeds the chronic risk LOC (1)

Acute RQs for birds exposed to MMA are presented below in Table 22. As with terrestrial mammals, most RQs, with the exception of granivores, exceed the restricted use and endangered species LOCs of 0.2 and 0.1 while some also exceed the high risk LOC of 0.5. For DMA, minimal acute risk to birds is presumed. DMA is practically non-toxic to birds and maximum residues on avian food items are not expected to exceed levels of concern at any use site. Chronic RQs for birds exposed to MMA or DMA have not been calculated due to lack of data.

Table 22. Risk Quotients for Birds from Exposure to MMA

Crop (Chemical)	Acute RQ [1]		
	Herbivores	Insectivores	Granivores
Cotton	0.16*	<0.1	<0.1
Non-crop	1.53***	0.86***	0.1*
Orchard	0.54***	0.30**	<0.1
Turf; max	1.33***	0.75***	<0.1
Turf; golf	0.89***	0.50***	<0.1

[1] RQ = EEC /LC50; LC50s = 4695 mg/kg (DSMA) and 1667 mg/kg (MSMA), both for northern bobwhite, adjusted for purity of the test material.
*** exceeds LOCs for high risk (0.5), restricted use (0.2), and endangered species (0.1)
** exceeds the LOCs for restricted use and endangered species
* exceeds the LOC for endangered species

d. Terrestrial and Semi-Aquatic Plants

Risk quotients for terrestrial and semi-aquatic plants exposed to drift and/or runoff are summarized below in Table 23 for MMA and Table 24 for DMA. For MMA, most RQs for endangered and non-endangered plants, both upland and semi-aquatic, exceed the LOC of 1 for exposure from runoff and drift. None of the drift-only RQs exceed the LOC. For DMA, no LOCs are exceeded for the use on cotton. The DMA non-crop and orchard uses exceed the LOC for endangered and non-endangered semi-aquatic plants

Table 23. Risk Quotients for Terrestrial and Semi-Aquatic Plants from Exposure to DSMA or MSMA

Crop (Chemical)	Non-Endangered RQs [1]			Endangered RQs [2]		
	Upland[3]	Semi-Aquatic[3]	Drift Only	Upland[3]	Semi-Aquatic[3]	Drift Only
Cotton	<1	<1	<1	<1	3*	<1
Non-crop	2*	17*	<1	13*	109*	<1
Orchard	<1	1.5*	<1	<1	6*	<1
Turf; golf	1.7*	15*	<1	11*	95*	<1
Turf; max	1.1*	9.8*	<1	7.4*	63*	<1

[1] RQ = EEC / EC25. For total loading use seedling emergence EC25 (1.25 and 0.116 lb ai/A for DSMA and MSMA, respectively). For drift use vegetative vigor EC25 (0.354 and 0.418 lb ai/A for DSMA and MSMA, respectively)
[2] RQ = EEC / NOEC. For total loading use seedling emergence NOEC (0.30 and 0.018 lb ai/A for DSMA and MSMA, respectively). For drift use vegetative vigor NOEC (<0.30 and 0.14 lb ai/A for DSMA and MSMA, respectively)
[3] Upland EEC based on sheet runoff + drift; Semi-Aquatic EEC based on channelized runoff + drift.
* exceeds the LOC (RQ $\geq$1) for nontarget plants

Table 24. Risk Quotients for Terrestrial and Semi-Aquatic Plants from Exposure to DMA

Crop (Chemical)	Non-Endangered RQs [1]			Endangered RQs [2]		
	Upland[3]	Semi-Aquatic[3]	Drift Only	Upland[3]	Semi-Aquatic[3]	Drift Only
Cotton	<1	<1	<1	<1	<1	<1

Noncrop	<1	4.5*	<1	<1	6.2*	2.7*
Orchard	<1	2.8*	<1	<1	3.8*	1.7*

[1] RQ = EEC / EC25. For total loading use seedling emergence EC25 (0.92 lb ai/A). For drift use vegetative vigor EC25 (0.12 lb ai/A)
[2] RQ = EEC / NOEC. For total loading use seedling emergence NOEC (0.67 lb ai/A). For drift use vegetative vigor NOEC (0.03 lb ai/A)
[3] Upland EEC based on sheet runoff + drift; Semi-Aquatic EEC based on channelized runoff + drift.
* exceeds the LOC (RQ ≥1) for nontarget plants

3. Ecological Incidents

The Ecological Incident Information System database included several ecological incidents possibly related to use of organic arsenicals. The majority of these incidents involved damage to treated plants, both turf and cotton (MSMA – 4 incidents; DSMA – 2 incidents; CAMA – 11 incidents). The certainty that these incidents were the result of organic arsenical herbicide use was rated “possible” in all of these incidents but one, which was rated “probable.” Other ecological incidents included two reports of damage to nearby vegetable plants from treatment of rights-of-way with MSMA. Additionally, there was one report of a dead bird found after treatment with cacodylic acid and one reported fish kill in a canal receiving runoff from golf courses treated with MSMA. In all of these incidents, the certainty that the effects were the result of use of arsenicals was rated “possible.”

4. Endangered Species Risk

EPA’s screening level assessment predicts that the organic arsenical herbicides will have no direct acute effects on threatened and endangered aquatic organisms. The risk assessments also indicate that RQs exceed endangered species LOCs for endangered terrestrial animals and plants. Further, potential indirect effects to any species, dependent upon a species that experiences effects from use of organic arsenical herbicides, cannot be precluded based on the screening level ecological risk assessment. These findings are based solely on EPA’s screening level assessment and do not constitute “may affect” findings under the Endangered Species Act.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decisions

A. Public Comments and Responses

Through EPA’s public participation process, EPA worked extensively with stakeholders and the public to reach the regulatory decisions for MSMA, DSMA, CAMA, and cacodylic acid. During the public comment period on the risk assessments, which closed on June 5, 2006, the Agency received ten comments from the following respondents: MAATF, Scotts Company, Florida Department of Environmental Protection (DEP), Florida Department of Agriculture and Consumer Services (DACS), Golf Course Superintendents Association of America (GCSAA), Wood Preservative Science Council (WPSC), and two individuals. The MAATF’s comments presented alternative approaches to assessing environmental fate and dietary exposure. Florida DEP and DACS’s comments emphasized the need for a better understating of the environmental fate and transport of the organic arsenical herbicides, especially in areas like Florida where a large amount of drinking water comes from ground water. GCSAA's comments supported the continued use of organic arsenical herbicides to support efficacious and cost-effective weed control. WPSC's comments presented an alternative way to assess background levels of arsenic. One individual's comments included two posters presented by the Canadian Wildlife Service. The other individual's comment expressed a concern of continued use of organic arsenical herbicides on athletic fields. Additional public comments received after the comment period included several submissions of two form letters supporting the reregistration of MSMA and DSMA. All comments and EPA's official responses are available at http://www.regulations.gov in docket number EPA-HQ-OPP-2006-0201.

B. Benefits and Alternatives

As part of the reregistration eligibility determination, EPA assessed the benefits and alternatives for each organic arsenical herbicide use. In general, EPA finds only limited benefits associated with the use of MSMA, DSMA, CAMA, and cacodylic acid, based on steadily declining use and the availability of effective alternatives. A summary of alternatives assessment findings and conclusions is provided below; the full alternatives assessment for major uses of these chemicals is available at http://www.regulations.gov in docket number EPA-HQ-OPP-2006-0201.

1. Cotton

Use in cotton has steadily declined since the late-1990s as alternative weed control strategies (e.g., Round-up® ready cotton) have become more prevalent. Additionally, EPA estimates that approximately no more than 6% of all cotton grown in the US is treated with MSMA or DSMA. Cacodylic acid shows little use in the US in recent years. DSMA and MSMA are used as post-emergent weed control, and cacodylic acid is used as a pre-plant burn down weed control and as a cotton harvest aid (desiccant/defoliant). For weed control, in addition to glyphosate (Round-up®) alternatives include diuron, norflurazon, pendimethalin, trifluralin, fluazifop and halosulfuron-methyl among others, depending on timing of application and the weed complex that needs to be controlled. For the harvest-aid use of cacodylic acid, alternatives include ethephon, dimethipin, thidiazuron and sodium chlorate, among others. EPA estimates that the impact of using alternatives is a decrease in net cash return to growers of approximately 6%. Because use has steadily declined, the current per cent of crop treated is small, alternatives are readily available for the sub-set of growers who use arsenicals, and the impact on net revenues from switching to these alternatives is relatively small, EPA concludes that the benefits of organic arsenical herbicide use on cotton are not compelling in light of the possible cancer risk from drinking water contamination.

2. Turf

Turf uses for the organic arsenical herbicides include grasses grown for seed, lawns, ornamental turf, sod farms, turfgrass, and turf grown for sod. Many alternatives exist to control weeds on turf including fluazifop and dithiopyr for postemergence control and dithiopyr or pendimethlin for preemergent control of crabgrass. The primary manner in which grass weeds such as crabgrass and dallisgrass can be effectively controlled is through the maintenance of a high quality turf such as is the case in almost all golf courses. However, when chemical control of grass weeds is needed, typically, two or more alternative chemicals would be required to achieve weed control comparable to the organic arsenicals. Preemergence products are typically highly effective at controlling crabgrass seedlings. However, the post emergent alternatives for the organic arsenical herbicides either control a narrow spectrum of weeds, or they are not effective on the more difficult grass weeds like dallisgrass (*Paspalum dilatatum*). Thus, multiple herbicides used in combination can be considered an alternative to the organic arsenical herbicides, but no single herbicide can be considered a direct replacement. Alternatives vary in price from slightly less expensive to considerably more expensive than the organic arsenicals.

Because there are both chemical and non-chemical alternatives available and any additional costs of using the alternatives will be borne by those using and benefiting from the improved turf, EPA concludes that the benefits of organic arsenical herbicide use on turf are not compelling in light of the possible cancer risk to the general population from drinking water contamination due to the use of these compounds.

3. Other Uses

Relatively small amounts of the organic arsenical herbicides are also used in nonbearing orchards and vineyards, noncrop areas, ornamentals, and nonbearing citrus. Similar to cotton, the organic arsenical herbicides are used for generalized weed control in these areas. Similar to weed control in cotton, comparable efficacy in these areas can likely be achieved through a combination of agents. In addition, EPA's Screening Level and Usage Analysis indicate that use in these areas are minimal compared to cotton and turf uses. Because the use is relatively small and alternatives are readily available, the benefits of retaining organic arsenical herbicide use on nonbearing orchards and vineyards, noncrop areas, ornamentals, and nonbearing citrus are thought to be limited.

C. Determination of Reregistration Eligibility and Regulatory Rationale

1. Reregistration Eligibility Decision

Section 4(g)(2)(A) of FIFRA calls for EPA to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. EPA has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing MSMA, DSMA, CAMA, or cacodylic acid as an active ingredient. The Agency has reviewed these generic data, and has determined that the data are sufficient to support a reregistration eligibility decision for all products containing MSMA, DSMA, CAMA, or cacodylic acid. EPA considered the available information and has concluded that all currently registered uses of MSMA, DSMA, CAMA, and cacodylic acid are not eligible for reregistration. This conclusion is based on EPA's finding of limited benefits, adequate alternatives, and drinking water cancer risk exceeding the Agency's level of concern. EPA concludes that the risks of continued use on all sites outweigh the limited benefits of weed control.

2. Regulatory Rationale for EPA's Reregistration Eligibility Decision

EPA's decision under FIFRA is based on a thorough evaluation of both the risks and benefits of the uses of the organic arsenical herbicides. The Agency's primary concern is the potential for applied organic arsenical products to transform to a more toxic inorganic form of arsenic in soil with subsequent transport to drinking water. In addition, EPA also identified some risk associated with the direct use of the organic arsenical herbicides.

Dietary exposure from drinking water alone results in risks that exceed OPP's level of concern for excess cancer risk (1×10^{-6}). Estimated drinking water concentrations for turf result in an excess cancer risk of 3×10^{-3}. EDWCs for cotton result in an excess cancer risk of 3×10^{-4}. These risk conclusions are supported by limited monitoring data in areas with high organic arsenical herbicide use. In addition, occupational handler dermal MOEs exceed LOCs; postapplication worker dermal MOEs exceed LOC; residential oral postapplication MOEs exceed LOC for CAMA and cacodylic acid; and ecological risk quotients exceed LOCs.

EPA explored potential mitigation measures to reduce exposure and risk. EPA met with the technical registrants to explore the possibility of labeling changes to reduce risks while preserving the efficacy and usability of the active ingredients and associated end-use products. The following labeling change options were considered:

- Limit golf course use to tees, fairways, and roughs only (MSMA, DSMA, CAMA)
- Limit turf applications to 1 broadcast treatment and up to 3 subsequent spot treatments not to exceed 10% of the treatment area (MSMA, DSMA, CAMA)
- Limit turf applications to four total applications of any combination of MSMA, DSMA, CAMA
- Reduce maximum labeled rate to 3.7 lbs. ai/A for CAMA
- Prohibit application to impervious surfaces in residential areas
- Prohibit aerial application (except cotton)
- Require chemical resistant gloves for occupational handlers mixing and loading MSMA, DSMA, CAMA, or cacodylic acid
- Require chemical resistant gloves for occupational handlers applying MSMA, DSMA, CAMA, or cacodylic acid with handheld equipment

- Restricting the high application rate of cacodylic acid for lawn renovation to certified applicators or those operating under the supervision of a certified applicator

After careful consideration of these options, the Agency has concluded that implementation of these measures would reduce certain risks; but that cancer risks through drinking water exposure would remain, for the most part, unchanged. When risk estimates are recalculated with the proposed mitigation above, excess cancer risk for cotton use is 3×10^{-4} (3.9 ppb) and excess cancer risk for turf use is 1×10^{-3} (13.1 ppb). Even with extensive mitigation beyond what was offered by the registrants, EPA believes the large disparity between the estimated risks and OPP's level of concern for excess cancer risk of 1×10^{-6} (equivalent to 0.02 ppb of inorganic arsenic) precludes risk reduction sufficient to reduce levels below OPP's level of concern.

Given that estimated drinking water exposure from the pesticidal uses alone exceeds EPA's level of concern and that alternative herbicides are readily available, EPA concludes that the benefits do not outweigh the risks and that all uses for the active ingredients MSMA, DSMA, CAMA, and cacodylic acid are ineligible for reregistration.

D. Food Quality Protection Act Findings and Regulatory Rationale

1. FFDCA/FQPA Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with the organic arsenical herbicides. EPA has determined that risk from dietary (food + water) exposure to inorganic arsenic exceeds the "risk cup." EPA did not aggregate drinking water exposure with food or residential exposures because the risks posed by drinking water alone are above the LOC and further combination would result in increased risk estimates that would further exceed the LOC. EPA considered the available information and has concluded that the tolerances listed under 40 CFR §180.289 (a)(1) and 40 CFR §180.311 (a)(1) do not meet the reasonable certainty of no harm standard under FFDCA/FQPA.

b. Tolerance Reassessment Summary

Table 25 presents a summary of the organic arsenical herbicides tolerance reassessment decision. EPA has determined that the 4 established tolerances for MMA and DMA do not meet the safety standards under Section 408(b)(2)(D) of the FFDCA, as amended by FQPA. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices, and the environmental behavior of the organic arsenical herbicides. The proposed revocation of the 4 tolerances will be announced in the Federal Register.

Table 25. Tolerance Reassessment Summary for the Organic Arsenical Herbicides

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment
Tolerances Listed Under 40 CFR §180.289 (a)(1) – MSMA/DSMA			
Cotton, undelinted seed	0.7	Revoke	This tolerance does not meet the reasonable certainty of no harm standard under FFDCA/FQPA.
Cotton, hulls	0.9	Revoke	This tolerance does not meet the reasonable certainty of no harm standard under FFDCA/FQPA.
Fruit, citrus	0.35	Revoke	Citrus is not being supported for reregistration.
Tolerance Listed Under 40 CFR §180.311 (a)(1) – Cacodylic Acid			
Cotton, undelinted seed	2.8	Revoke	This tolerance does not meet the reasonable certainty of no harm standard under FFDCA/FQPA.

No Codex or Canadian MRLs have been established for MSMA, DSMA, CAMA, or cacodylic acid.

FDA has established tolerances for total arsenic residues in edible tissues and in eggs of chickens and turkeys as well as in edible tissues of swine as listed under 21 CFR § 556.60. These tolerances are regulated by FDA and are not included in this tolerance reassessment decision; however, the possible residues from these uses are included in EPA's dietary risk assessment.

c. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use its authorities under FIFRA and/or the FFDCA to require any necessary data on endocrine-related effects. As the science develops and resources allow, screening for additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

In the available toxicity studies on MSMA, DSMA, CAMA, and cacodylic acid, there was no evidence of endocrine disruption effects.

d. Cumulative Risks

Risks summarized in this document are those that result only from the use of the organic arsenical herbicides. The Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to the organic arsenical herbicides. EPA has not assumed that the organic arsenical herbicides share a common mechanism of toxicity with other compounds.

2. Regulatory Rationale for FFDCA/FQPA Findings

While EPA has identified some risk associated with the direct use of the organic arsenical herbicides, the Agency's primary concern is the potential for applied organic arsenical products to transform to a more toxic inorganic form of arsenic in soil with subsequent transport to drinking water.

Dietary exposure from drinking water alone results in risks that exceed OPP's level of concern for excess cancer risk (1×10^{-6}). Estimated drinking water concentrations for turf result in an excess cancer risk of 3×10^{-3}. EDWCs for cotton result in an excess cancer risk of 3×10^{-4}. These estimates may overestimate inorganic arsenic exposure and risk because the exposure is known to be to a combination of organic and inorganic arsenic compounds; however, limited monitoring data in areas with high organic arsenical herbicide use support EPA's risk assessment.

In order for a pesticide tolerance to remain in effect, EPA must generally determine with reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue. Because the potential pesticide chemical residues in drinking water alone exceed EPA's LOC, the Agency did not conduct an aggregate exposure assessment for inorganic arsenic. Further aggregation with other exposure sources (i.e., food, residential application and post-application activities, or background sources) would have resulted in increased risk estimates that would have further exceeded the LOC.

Given that estimated drinking water exposure from the pesticidal uses alone (i.e., without food, residential application and post-application activities, or background sources) exceeds EPA's level of concern, EPA concludes that existing tolerances listed under 40 CFR §180.289 (a)(1) and 40 CFR §180.311 (a)(1) do not meet the reasonable certainty of no harm standard under FFDCA/FQPA.

E. Policy Considerations

EPA's Office of Water establishes the maximum contaminant level (MCL) for total arsenic in drinking water. This regulation was established to reduce potential cancer risks from background arsenic in drinking water. While the MCL indicates the maximum allowable concentration of arsenic in drinking water (10 ppb), the MCLg (MCL goal) or target concentration of arsenic in drinking water is zero (0 ppb). The MCL represents the highest acceptable level of exposure based on technological and economic limitations, and the MCLg represents the target level based on adverse human health effects.

Although estimated arsenic exposure in drinking water resulting from pesticidal uses may, in some cases, be lower than the MCL, allowing additional arsenic exposure in drinking water as a result of organic arsenical herbicide use would not be consistent with EPA's goal to minimize arsenic exposure. Continued use of the organic arsenical herbicides would result in three undesired effects: unnecessary arsenic exposure to individuals using un-treated water sources; unnecessary arsenic exposure to individuals using treated water sources that have arsenic levels typically below the MCL; and additional economic burden to water treatment plants typically above the MCL that would need to remove additional arsenic from herbicidal use to "clean" water down to the MCL. Use of organic arsenic herbicides results in an additional, man-made, and preventable source of arsenic exposure and does not provide meaningful benefit to society. Thus, OPP's reregistration eligibility and tolerance reassessment decisions are in harmony with broader EPA policy to protect human health and the environment by minimizing exposure to arsenic.

V. What Registrants Need to Do

EPA has determined that all uses for MSMA, DSMA, CAMA, and cacodylic acid are ineligible for reregistration and that the associated tolerances do not meet the reasonable certainty of no harm standard. EPA is issuing this Reregistration Eligibility Decision (RED) document for the organic arsenical herbicides, as announced in a Notice of Availability published in the Federal Register. There is a 60-day public comment period for this document.

In the near future, EPA intends to initiate appropriate action to revoke tolerances that do not meet the reasonable certainty of no harm standard identified in this RED. Also, in the absence of voluntary cancellation requests or substantive comments that affect EPA's ineligibility decision, EPA intends to initiate cancellation proceedings for the registrations of pesticide products that are declared ineligible in this RED. These actions will be announced in the Federal Register and will provide interested persons with an opportunity to request a hearing for cancellation actions under FIFRA or to comment and file objections for tolerance proceedings under the FFDCA/FQPA.

Appendix A. Use Patterns Subject to Reregistration for the Organic Arsenical Herbicides

Appendix A. Use Patterns Subject to Reregistration for the Organic Arsenical Herbicides

All uses for MSMA are ineligible for reregistration.

All uses for DSMA are ineligible for reregistration.

All uses for CAMA are ineligible for reregistration.

All uses for cacodylic acid are ineligible for reregistration.

Appendix B. Data Supporting Guideline Requirements for the Reregistration of the Organic Arsenical Herbicides

Appendix B. Data Supporting Guideline Requirements for the Reregistration of the Organic Arsenical Herbicides

Data Requirement			Use Pattern	Citations
New Guideline Number	Old Guideline Number	Description		
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Composition	All	42388301, 42053701, 42361001, 42051902, 41602701, 42387801, 41702001, 42474101, 41702002, 42153501, 41608101, 42913801
830.1700	61-3	Discussion of Formation of Impurities	All	42053701, 42361001, 42053702, 41602701, 41702001, 42474101, 41702002, 42913801
830.1700	62-1	Preliminary Analysis	All	41608302, 42614501, 44150401,42053702, 42825901
830.1750	62-2	Certification of Limits	All	41608302, 42614501, 42053702,
830.1800	62-3	Analytical Method	All	42387802, 42825901
830.6302	61-2	Description of Beginning Materials and Manufacturing Process	All	40957813, 42053701, 44150401, 42361001, 41602701, 42387801, 41702001, 42474101, 41702002, 42081201, 42913801
830.6302	63-0	Reports of Multiple phys/chem Characteristics	All	42473801, 42451102, 42451101
830.6302	63-2	Color	All	42807602
830.6303	63-3	Physical State	All	42807603
830.6304	63-4	Odor	All	42807604
830.6313	63-13	Stability to normal and elevated temperatures, metals, and metal ions	All	41610001, 42378601, 42807609
830.7000	63-12	pH	All	41982002, 42378601, 42807608,
830.7200	63-5	Melting Point	All	42397101, 42403501, 41982001, 41789501, 42807605,
830.7300	63-7	Density	All	42807606
830.7370	63-8	Solubility	All	42403501, 41602502, 41610001, 42807607
830.7370	63-10	Dissociation Constants in Water	All	41976201, 41610001
830.7550	63-11	Partition coefficient, shake flask method	All	41976202, 40957813
830.7950	63-9	Vapor Pressure	All	42120701, 41651901,
ECOLOGICAL EFFECTS				

Data Requirement			Use Pattern	Citations
New Guideline Number	Old Guideline Number	Description		
850.2100	71-1	Avian Single Dose Oral Toxicity	All	41608304, 42551302, 41892001, 41610002, 43316403,
850.2200	71-2	Avian Dietary Toxicity	All	42551301, 42551302, 41610003, 41610004, 41892002, 41892003, 43316401, 43316402
850.1075	72-1	Acute Toxicity to Freshwater Fish	All	40098001, 41748302, 41748301, 41608304, 41610002, 43316403, 41747301, 41748001, 41905601, 41905602
850.1010	72-2	Acute Toxicity to Freshwater Invertebrates	All	41747901, 42551301, 41940605
850.4230	123-1	Seed germination/seedling emergence and vegetative vigor	All	41732301,41732302, 41905604, 41905603
850.4400	123-2	Aquatic plant growth	All	41791105, 41791101, 41791104, 41791102, 41791103
875.2100	132-1	Dissipation of Dislodgeable Foliar & Soil Residues	All	44958901
875.2400	133-3	Dermal passive dosimetry expo	All	44459801
875.2500	133-4	Inhal. passive dosimetry expo	All	44459801
850.1045	72-3	Panaeid Acute Toxicity Test	A, B, D	42433301, 42433302 42468101, 42414102, 42464801, 42414101,
850.3020	141-1	Honey bee acute contact LD50	All	41608310, 41935401
850.4400	123-2	Aquatic Plant Toxicity	A, B, D	41791101, 41940603, 43184501, 43184502, 43184503
TOXICOLOGY				
870.3100	82-1	Subchronic Oral Toxicity: 90-Day Study	All	42767701, 42362501
870.4200	83-2	Oncogenicity	All	40632601
870.3700	83-3	Teratogenicity -- 2 Species	All	40625701, 41926401, 159390, 40663301
870.4100	83-1	Chronic Toxicity	All	40546101, 41266401, 41490901
870.5380	84-2	Interaction with Gonadal DNA	All	41651902, 41651903, 41651904, 41651905
870.1100	81-1	Acute Oral Toxicity - Rat	All	105171, 41892004, 45405601
870.2400	81-4	Primary Eye Irritation - Rabbit	All	43840901
870.3200	82-2	21-Day Dermal – Rabbit/Rat	A, B, D	41872801, 41872701, 42659701

Data Requirement			Use Pattern	Citations
New Guideline Number	Old Guideline Number	Description		
870.3465	82-4	90-day inhal.-rat	All	44700301, 43178301
870.3800	83-4	2-Generation Reproduction – Rat	A, B, D	43178301, 41059501, 41652201
870.4300	83-5	Combined Chronic Toxicity/Carcinogenicity: Rats	A, B, D	41669001, 41862101, 42173201, 41914601
870.5100	84-2	Bacterial Reverse Gene Mutation	A, B, D	
870.5300	84-2	Gene Mutation (CHO)	A, B, D	
870.7485	85-1	General Metabolism	A, B, D	42010501, 42341301
870.7600	85-3	Dermal Penetration/Absorption	All	43497401
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis	A, B, D	42363001, 42059201
835.2240	161-2	Photodegradation - Water	A, B, D	41903902, 41662601,
835.2410	161-3	Photodegradation - Soil	A, B, D	41651906, 41662602, 41903901
835.4100	162-1	Aerobic Soil Metabolism	A, B, D	44767601, 42616001,
835.4300	162-4	Aerobic Aquatic Metabolism	A, B, D	43314801, 43036101
835.4400	162-3	Anaerobic Aquatic Metabolism	A, B, D	44767602, 42572601
835.6100	164-1	Terrestrial Field Dissipation	A, B, D	42843101, 4348530, 41302101, 92015007, 43485301, 42526001, 42616201, 117165
RESIDUE CHEMISTRY				
860.1850	165-1	Confined Accumulation in Rotational Crops	A, B, D	43091101
860.1300	171-4A2	Nature of the Residue in Plants	All	42886601, 42324401, 42391201, 43013401, 42216101, 42324401
860.1300	171-4A3	Nature of the Residue in Livestock	All	42975001, 43059901, 42009701, 42009702, 42525002 42525001
860.1300	171-4B	Nature of Residue – Livestock (Goat)	A, B, D	44415202, 45936601, 45936602, 42009702, 43279301, 43630101, 43630201, 43769101, 43802501, 44125501, 44825201
860.1340	171-4C	Residue Analytical Method – Plants	A, B, D	44320001, 44325801, 44325802, 44087401, 44415201, 44415203, 42525001, 42525002, 43605901, 43817101, 43605901, 43683101, 43720701, 43803701, 43817101, 43959801, 44195901,
OTHER				
Non-guideline	Non-guideline	Complete primary report --	A, B, D	10991

Data Requirement			Use Pattern	Citations
New Guideline Number	Old Guideline Number	Description		
Study	Study	experimental research		
Non-guideline Study	Non-guideline Study	Secondary report attributed to others	All	46565301
Non-guideline Study	Non-guideline Study	Complete primary report -- experimental research	All	44972201, 45496802, 45496803, 41054701, 46436501, 46436502, 46436503, 46436504, 46671701, 44195901, 43605901

Appendix C. Technical Support Documents

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room S-4400, One Potomac Yard (South Building), 1777 S. Crystal Drive, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 AM to 4:00 PM.

The preliminary risk assessments and related documents for the organic arsenical herbicides are available in the public docket and in e-dockets under docket number EPA-HQ-OPP-2006-0201. During the public comment period, respondents submitted comments and additional information on the organic arsenical herbicides. EPA reviewed and, where appropriate, incorporated this information into the revised risk assessments. These revised risk assessments form the basis of the regulatory decision described in this RED. These risk assessment and related documents are available under docket number EPA-HQ-OPP-2006-0201.

Technical support documents for the organic arsenical herbicides RED include the following:

<u>Human Health Effects Documents</u>

1. ORGANIC ARSENICS: Final HED Combined Chapter of the Reregistration Eligibility Decision Document (RED). D329694. June 21, 2006.
2. Organic Arsenicals. Revised Acute and Chronic Dietary Exposure Assessments for the Reregistration Eligibility Decision (RED). D329695. June 21, 2006.
3. Arsenic: Final Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document for DMA, CAMA, MSMA, and DSMA. D329696. June 21, 2006.
4. Revised and updated executive summaries for Cacodylic acid (Dimethylarsinic acid) and Methanearsonic Acid and the relevant sodium and calcium salts. DP309103. February 2, 2006.
5. Residue Chemistry Chapter for the Monosodium and Disodium Salts of Methanearsonic Acid Reregistration Eligibility Decision (RED). D309106. January 31, 2006.
6. Residue Chemistry Chapter for the Cacodylic Acid and Salts Reregistration Eligibility Decision (RED) Document. D309106. January 31, 2006.
7. Revised Science Issue Paper: Mode of Carcinogenic Action for Cacodylic Acid (Dimethylarsinic Acid, DMA^{V}) and Recommendations for Dose Response Extrapolation. January 30, 2006

<u>Environmental Fate and Effects Documents</u>

1. Drinking Water Assessment for Organic Arsenical Herbicides for the Reregistration Eligibility Decision (RED). D309097. March 29, 2006.
2. Addendum to EFED RED Chapters for Organic Arsenicals Accounting for Updated Label Rates and Potential for Long Term Buildup in Soil. D309100. February 3, 2006.

3. Re-registration Eligibility Document for Sodium and Calcium Salts of Methanearseonic Acid (MSMA/DSMA/CAMA). D277223. September 24, 2001.
4. Environmental Risk Science Chapter for Cacodylic Acid and its Sodium Salt. D210451. March 27, 2000.

Biologic and Economic Analysis Documents

1. Alternatives Assessment of the Organic Arsenical Herbicides Used in Residential and Golf Course Turfgrass, and Cotton. D309117. April 12, 2006.

Appendix D. Citations Considered to be Part of the Data Base Supporting the Reregistration Eligibility Decision

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MRID	Citation Reference
10991	Meisch, M. (1972) Altosid^(TM)I 4E: Test No. E-36-Del-72. (Unpub- lished study received Dec 22, 1972 under 3G1343; submitted by Zoecon Corp., Palo Alto, Calif.; CDL:095220-U)
105171	Cannelongo, B.; Sabol, E.; Soliz, D.; et al. (1982) Rat Acute Oral Toxicity: Project No. 2558-82. (Unpublished study received Jun 21, 1982 under 38167-1; prepared by Stillmeadow, Inc., sub- mitted by Setre, Inc., Memphis, TN; CDL:247705-A)
117165	Sandberg, G.; Allen, I.; Dietz, E. (1973) Arsenic Residues in Soils Treated with Six Annual Applications of MSMA and ... CA: Project No. 32532-73312. Progress rept., 73 Wes 8-9-10. (Unpublished study received Aug 27, 1976 under 6308-18; submitted by Ansul Chemical Co., Weslaco, TX; CDL:095256-C)
159390	Rubin, Y. (1986) Methanearsonic Acid: Teratology Study in the Rab- bit: PAL/006/MSM. Unpublished study prepared by Life Science Research Israel Ltd. 170 p.
40098001	Mayer, F.; Ellersieck, M. (1986) Manual of Acute Toxicity: Inter- pretation and Data Base for 410 Chemicals and 66 Species of Freshwater Animals. US Fish & Wildlife Service, Resource Pub- lication 160. 579 p.
40546101	Waner, T.; Nyska, A. (1988) Methanearsonic Acid: Fifty-two Week Chronic Oral Toxicity Study in Beagle Dogs: Document Number PAL/MAA/022. Unpublished study prepared by Life Science Re- search Israel, Ltd. 449 p.
40625701	Gal, N.; Rubin Y. (1988) Cacodylic Acid: Teratogenicity Study in the Rat: LSRI Proj. No. PAL/017/CAC. Unpublished study prepared by Life Science Research Israel Ltd. 261 p.
40632601	Fermenta Plant Protection Co. (1988) Justification for Dose Select- ion in New Methanearsonic Acid (MAA) Mouse Oncogenicity Study. Unpublished compilation. 184 p.
40663301	Rubin, Y.; Nyska, A. (1988) Cacodylic Acid: Teratogenicity Study in the Rabbit: LSRI Project No. PAL/019/CAC. Unpublished study prepared by Life Science Research Israel Ltd. 152 p.
40957813	Bellet, E. (1988) Product Chemistry for 3.25 Cacodylate. Unpub- lished study prepared by Luxembourg-Pamol, Inc. 8 p.
41054701	Knarr, R. (1988) Exposure of Applicators to Propoxur During Trigger Pum Spray Application of a Liquid Product: 99100. Unpublished study prepared by Mobay Corp. 195 p.
41266401	Waner, T.; Nyska, A. (1988) Methanearsonic Acid Fifty-two Week Chronic Oral Toxicity Study in Beagle Dogs: Doc. No. PAL/008/MAA. Unpublished study prepared by Life Science Research Israel, Ltd. 48 p.
41302101	Woolson, E. (1989) Terrestrial Field Dissipation of Cacodylic Acid on Turf: Lab Project Number: 127-001: EF-88-43. Unpublished study prepared by EPL Bio Analytical Services, Inc. 294 p.
41490901	Zomber, G.; Nyska, A.; Waner, T.; et al. (1989) Cacodylic Acid: 52- Week Oral Toxicity Study in Beagle Dogs: Lab Project Number: PAL/012/CAC. Unpublished study prepared by Life Science Resea- rch Israel Ltd. 751 p.
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41608310 Hoxter, K.; Smith, G. (1990) 3. 25 Cacodylic Acid: An Acute Contact Toxicity Study with the Honey Bee: Lab Project Number: 286-101. Unpublished study prepared by Wildlife International Ltd. 13 p.

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41662601 Lawrence, B.; Kesterson, A. (1990) Solution Photolysis of ?carbon- 14| Cacodylic Acid in Natural Sunlight: Lab Project Number: 455. Unpublished study prepared by Pharmacology & Toxicology Research Laboratory. 71 p.

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